

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and)	
SANOFI-AVENTIS U.S. LLC,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 07-792 (GMS) (MPT)
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	

**DECLARATION OF KATHRYN M. LIBERATORE
IN SUPPORT OF PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS
MOTION TO ENJOIN SECOND FILED, DUPLICATIVE LITIGATION**

I, Kathryn M. Liberatore, declare:

I am an attorney with the law firm Kirkland & Ellis LLP, counsel for sanofi-aventis and sanofi-aventis U.S. LLC. I submit this declaration in support of Plaintiffs' Opening Brief In Support Of Its Motion To Enjoin The Parties From Prosecuting Second Filed, Duplicative Litigation and have personal knowledge of the facts set forth herein.

1. Attached hereto as Exhibit A is a true and accurate copy of Apotex Inc. - Corporate Info, <http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes> (last visited March 4, 2008).

2. Attached hereto as Exhibit B is a true and accurate copy of a letter dated August 14, 2007 from Bernard C. Sherman to Sanofi-Aventis US and Sanofi-Aventis and Jagotec AG.

3. Attached hereto as Exhibit C is a true and accurate copy of a letter dated October 25, 2007 from Bernard C. Sherman to Sanofi-Aventis US and Sanofi-Aventis and Jagotec AG.

4. Attached hereto as Exhibit D is a true and accurate copy of the Complaint dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Actavis South Atlantic LLC, et al.*, Civil Action No. 07-572 (GMS) (MPT), in the District Court for the District of Delaware.

5. Attached hereto as Exhibit E is a true and accurate copy of the Complaint dated September 21, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Barr Laboratories, Inc.*, Civil Action No. 07-574 (GMS) (MPT), in the District Court for the District of Delaware.

6. Attached hereto as Exhibit F is a true and accurate copy of a letter dated October 1, 2007 from William T. Vuk to Bernice Tao.

7. Attached hereto as Exhibit G are true and correct copies of:

- excerpts from Defendants Apotex Inc.'s and Apotex Corp.'s Answer, Defenses, and Counterclaims dated June 11, 2007 filed in *Allergan, Inc. v. Apotex, Inc. and Apotex Corp.*, Civil Action No. 07-278-GMS, in the District Court for the District of Delaware;
- excerpts from Defendants Apotex Inc.'s and Apotex Corp.'s Answer, Defenses, and Counterclaims dated May 30, 2007 filed in *Medpointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-204-SLR, in the District Court for the District of Delaware;
- excerpts from Answer of Apotex Inc. and Apotex Corp. to Plaintiff's Amended Complaint, Affirmative Defenses and Counterclaims dated April 14, 2006 filed in *Medpointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 06-164 (SLR), in the District Court for the District of Delaware;
- excerpts from Defendant Apotex, Inc.'s Answer, Affirmative Defenses and Counterclaims dated May 9, 2006 filed in *Merck & Co., Inc. v. Apotex, Inc.*, Civil Action No. 06-230-GMS, in the District Court for the District of Delaware; and
- Complaint for Declaratory Judgment and Demand for Jury Trial dated October 29, 2003 filed in *Torpharm Inc., Apotex Corp., and Apotex, Inc., v. Pfizer Inc. and Warner-Lambert Company*, Civil Action No. 03-990, in the District Court for the District of Delaware.

8. Attached hereto as Exhibit H is a true and accurate copy of a letter dated December 6, 2007 from William T. Vuk to Dr. Bernard Sherman and Tammy McIntyre.

9. Attached hereto as Exhibit I is a true and accurate copy of an email dated December 11, 2007 from Maryellen Noreika to Sherry L. Rollo.

10. Attached hereto as Exhibit J is a true and accurate copy of a letter dated December 31, 2007 from Maryellen Noreika to Sherry L. Rollo.

11. Attached hereto as Exhibit K is a true and accurate copy of a letter dated January 7, 2008 from Steven E. Feldman to William T. Vuk.

12. Attached hereto as Exhibit L is a true and accurate copy of a letter dated January 7, 2008 from William T. Vuk to Steven E. Feldman.

13. Attached hereto as Exhibit M is a true and accurate copy of an email dated February 28, 2008 from James Parrett to Paul Molino, et al.

14. Attached hereto as Exhibit N is a true and accurate copy of Apotex Inc.'s and Apotex Corp.'s Response and Opposition to Plaintiffs' Motion For Transfer of Action Pursuant to 28 U.S.C. § 1407 filed on February 25, 2008 in MDL No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

15. Attached hereto as Exhibit O is a true and accurate copy of the Complaint dated December 10, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

16. Attached hereto as Exhibit P is a true and accurate copy of Plaintiffs' Motion to Transfer or Stay and Supporting Memorandum of Law dated January 8, 2008, without exhibits, filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*,

Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

17. Attached hereto as Exhibit Q is a true and accurate copies of Motion of Plaintiffs for Transfer to the District of Delaware Pursuant to 28 U.S.C. 5 1407 and Brief in Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. 5 1407, without exhibits, in MDL. No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

18. Attached hereto as Exhibit R is a true and accurate copy of the Answer of Apotex Inc. And Apotex Corp. To Complaint, Affirmative Defenses And Counterclaims dated December 28, 2007 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

19. Attached hereto as Exhibit S is a true and accurate copy of the Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses And Amended Counterclaims dated January 2, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

20. Attached hereto as Exhibit T is a true and accurate copy of Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures dated January 17, 2008 served in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

21. Attached hereto as Exhibit U is a true and accurate copy of a letter dated January 17, 2008 from William T. Vuk to Steven E. Feldman and Stephen J. Bronis.

22. Attached hereto as Exhibit V is a true and accurate copy of Plaintiffs' Initial Disclosures Pursuant To Rule 26(a)(1) dated January 31, 2008 served in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

23. Attached hereto as Exhibit W is a true and accurate copy of Defendants' First Request For The Production Of Documents And Things To Plaintiff, served January 18, 2008 in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

24. Attached hereto as Exhibit X is a true and accurate copy of Defendants' First Interrogatories To Plaintiffs, served February 8, 2008 in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

25. Attached hereto as Exhibit Y is a true and accurate copy of Plaintiffs' Responses And Objections To Defendants' First Request For Production Of Documents And Things To Plaintiff, served on February 19, 2008 in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

26. Attached hereto as Exhibit Z is a compendium of the unreported cases cited in Plaintiffs' Opening Brief In Support Of Its Motion To Enjoin Second Filed, Duplicative Litigation.

27. Attached hereto as Exhibit AA is a true and accurate copy of the Transcript of Scheduling Conference Before the Honorable Shelby Highsmith, United States

District Judge, dated July 10, 2000, from *Abbott Laboratories v. Andrx Corporation, et al.*, Civil Action No. 00-6500-CV-SH, in the District Court of the Southern District of Florida.

28. Attached hereto as Exhibit BB is a true and accurate copy of Plaintiffs' Motion For Status Conference And Incorporated Memorandum Of Law dated February 27, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

29. Attached hereto as Exhibit CC is a true and accurate copy of Defendants Apotex Inc.'s And Apotex Corp.'s Memorandum In Opposition To Plaintiffs' Motion To Transfer Or Stay dated January 28, 2008 filed in *sanofi-aventis and sanofi-aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-61800-CIV-MORENO/SIMONTON, in the District Court for the Southern District of Florida.

30. Attached hereto as Exhibit DD is a true and accurate copy of Defendants Actavis South Atlantic LLC's And Par Pharmaceutical, Inc.'s Response In Support Of Motion To Transfer And Consolidate filed on February 25, 2008 in MDL No. 1941, *In re Alfuzosin Hydrochloride Patent Litigation*.

I declare under penalty of perjury that the foregoing is true and accurate.

/s/ Kathryn M. Liberatore
Kathryn M. Liberatore
New York, New York

March 4, 2008
1751370

CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP

I further certify that I caused to be served copies of the foregoing document on March 4, 2008 upon the following in the manner indicated:

Richard L. Horwitz, Esquire
POTTER ANDERSON & CORROON LLP
Hercules Plaza – 6th Floor
1313 North Market Street
Wilmington, DE 19801

*VIA ELECTRONIC MAIL
And HAND DELIVERY*

Robert B. Breisblatt, Esquire
Steven E. Feldman, Esquire
Sherry L. Rollo, Esquire
WELSH & KATZ LTD.
120 S. Riverside Plaza
22nd Floor
Chicago, IL 60606

VIA ELECTRONIC MAIL

/s/ James W. Parrett, Jr. (#4292)

James W. Parrett, Jr. (#4292)

EXHIBIT A



Select a Country

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Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company. From its 2 employees, 5,000 square foot beginning, the company has grown to employ over 6,500 people in research, development, manufacturing and distribution facilities world-wide. The Canadian operations of the Apotex Group of Companies with approximately 5,800 employees now occupy over 3.4 million square feet in Montreal, Richmond Hill, Toronto, Etobicoke, Mississauga, Brantford, Windsor, Winnipeg, Calgary and Vancouver.

In the last few years, Apotex has hired over 1200 new employees in Production, Engineering, Operations, Quality and Research. Out of the total employee base, there are over 2,100 scientific staff including over 110 PhD's. To meet the growing world demand for Apotex medicines, hundreds of new qualified technical professionals need to be hired. Apotex produces more than 300 generic pharmaceuticals in over 4000 dosages and formats which, in Canada, are used to fill over 85 million prescriptions a year - the largest amount of any pharmaceutical company in this country.

[Chairman's Message](#) [President's Message](#)



Today, Apotex is a necessary and trusted member of Canada's healthcare community. The company's pharmaceuticals can be found in virtually every pharmacy and healthcare facility in Canada and are exported to over 115 countries around the globe. Export markets represent an ever growing portion of the total sales. Apotex has also established a presence through subsidiaries, joint ventures or licensing agreements in the Czech Republic, Mexico, China, Poland, New Zealand, France, and Italy, to name just a few. Healthcare professionals around the world rely on Apotex for quality and value.

Although the company's own business is developing and manufacturing generic pharmaceuticals, the success of Apotex has enabled it to diversify into a number of other health-related areas. The Apotex Pharmaceutical Group of Companies also researches, develops, manufactures and distributes fine chemicals, non-prescription and private label medicines, and disposable plastics for medical use.

The worldwide sales of the Apotex Group of companies exceed \$1 billion (Canadian \$) per year.

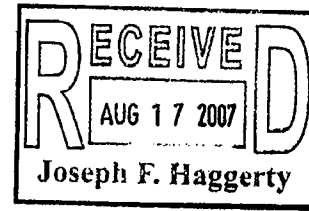
[Leading the Way With Research and Development](#)

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Last Modified: February 29, 2008 2:33:17 PM

EXHIBIT B



August 14, 2007



Sanofi-Aventis US
55 corporate Drive
Bridgewater, NJ 08807

and

Sanofi-Aventis and Jagotec AG
c/o Jacobson Holman PLLC
400 Seventh St. NW
Washington, DC 20004

Attention: Harvey B. Jacobson Jr.

Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of
the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Dear Sir or Madam:

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, we advise you, as the New Drug Application ("NDA") holder for the reference drug and the patent owner of the listed patent, that the United States Food and Drug Administration ("FDA") has received an Abbreviated New Drug Application ("ANDA") from Apotex Inc. (hereinafter "Apotex") for alfuzosin hydrochloride extended release tablets of 10 mg strength. Apotex's ANDA was submitted under 21 U.S.C. § 355(j)(1) and 2(A) with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of U.S. Patent No. 6149940 ("the '940 patent").

Required Disclosures under 21 C.F.R. § 314.95(c)

Pursuant to 21 C.F.R. § 314.95(c)(1), we advise you that FDA has received an ANDA from Apotex containing any required bioavailability or bioequivalence data or information from studies on alfuzosin hydrochloride extended release tablets.

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by Apotex has been assigned ANDA No. 79-013 by the FDA.

Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of Apotex's ANDA is "Alfuzosin Hydrochloride Extended Release Tablets".

Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active pharmaceutical ingredient of Apotex's proposed drug product is alfuzosin hydrochloride. The proposed method of administration is oral.

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patent in the paragraph IV certification, alleged to be not infringed is the '940 patent.

Detailed Statement

Apotex alleges, and has certified to the FDA, that in its opinion and to the best of its knowledge, each claim of the '940 patent will not be infringed by the commercial manufacture, use or sale of the drug product described by Apotex's ANDA No. 79-013. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(6), Apotex's detailed statement of the legal and factual basis for the certification set forth in Apotex's ANDA is as follows:

The claims of the '940 patent are limited to a tablet comprising at least two layers, one of which contains alfuzosin hydrochloride. Our tablets will not infringe because they do not comprise two or more layers but are comprised of a single homogenous matrix.

Apotex certifies pursuant to 21 C.F.R. § 314.95(c)(7) that:

Tammy McIntire
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FL 33326

Is hereby authorized to accept service of process on behalf of Apotex in connection with its ANDA No. 79-013 relating to alfuzosin hydrochloride extended release tablets.

Offer of Confidential Access to Application Pursuant to 21 U.S.C. § 355(j)(5)(c)

Apotex offers to provide confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(c)(i)(III) can be brought.

21 U.S.C. § 355(j)(5)(C)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also

grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential access:

1. Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in any patent prosecution for you or any FDA counseling, litigation or other work before or involving FDA. Such information (hereinafter, "Confidential Apotex Information") shall be marked "CONFIDENTIAL".
2. The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without one prior written consent.
3. As provided by § 355(j)(5)(c)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. Your outside law firm agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Information, and that all Confidential Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.
4. The Confidential Information disclosed is, and remains, the property of Apotex.
5. By providing the Confidential Information, Apotex does not grant your outside law firm any interest in or license for the Confidential Information. Your outside law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Information, return to Apotex, all Confidential Information and any copies thereof. Your outside law firm shall return all Confidential Information to Apotex before any infringement suit is filed by you. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Information that Apotex provides shall be included in any publicly-available complaint or other pleading.
6. Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or

infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance, or materiality of any such Confidential Information, document, or thing. The fact that Apotex provides Confidential Information upon your request shall not be construed as an admission by Apotex that such Confidential Information is relevant to the disposition of any issue relating to any alleged infringement of any patent, or to the validity or enforceability of any patent.

7. The attorneys from your outside law firm shall acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Information.

Section 355(j)(5)(C)(i)(III) further provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access", and that the "restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract". Thus, to the extent that you request access to Confidential Apotex Information, you mandatorily accept the terms and restrictions attached hereto. Written notice requesting access under this Offer of Confidential Access should be made to:

Bernice Tao
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Reservation of Legal Rights

Apotex reserves the right to allege the same, similar, different or new theories of non-infringement, invalidity, and/or unenforceability, and nothing in the Notice Letter or Detailed Statement shall be construed as to limit Apotex's rights to make any allegation in any subsequent litigation regarding any issue.

Yours very truly,

APOTEX INC.



Bernard C. Sherman, Ph.D., P.Eng.
Chairman and C.E.O.

EXHIBIT C



OCT 2007
RECEIVED

October 25, 2007

VIA REGISTERED MAIL -
RETURN RECEIPT REQUESTED

Sanofi-Aventis US
55 Corporate Drive
Bridgewater, NJ 08807

and

Sanofi-Aventis and Jagotec AG
c/o Jacobson Holman PLLC
400 Seventh St., NW
Washington, DC 20004

Attention: Harvey B. Jacobson Jr.

Re: Notice of Amended Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Para. IV Notice Letter for Alfuzosin ER; US Patent No. 4,661,491

Dear Sir:

Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, we advise you, as the New Drug Application ("NDA") holder for the reference drug and the patent owner of the listed patent, that the United States Food and Drug Administration ("FDA") has received Abbreviated New Drug Application No. 79-013 ("ANDA") from Apotex Inc. (hereafter "Apotex") for alfuzosin hydrochloride extended release tablets of 10 mg strength, and that Apotex has amended this ANDA under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of U.S. Patent No 4,661,491 ("the '491 patent") on January 18, 2011.

Required Disclosures under 21 C.F.R. § 314.95(c)

Pursuant to 21 C.F.R. § 314.95(c)(1), we advise you that the FDA has received an ANDA from Apotex containing any required bioavailability or bioequivalence data or information from studies on alfuzosin hydrochloride extended release tablets.

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by Apotex has been assigned ANDA No. 79-013 by the FDA.

Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of Apotex's ANDA is "Alfuzosin Hydrochloride Extended Release Tablets."

Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active pharmaceutical ingredient of Apotex's proposed drug product is alfuzosin hydrochloride. The proposed method of administration is oral.

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patent in the paragraph IV certification alleged to be invalid is the '491 patent.

Detailed Statement

Apotex Inc. ("Apotex") has requested approval for alfuzosin hydrochloride extended release tablets of 10 mg strength ("the Apotex Products") in ANDA No. 79-013. Apotex now seeks approval for the commercial manufacture, use, sale, offer for sale, and importation of the Apotex Products prior to the expiration of the '491 Patent.

Accordingly, Apotex sets forth this Detailed Statement, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), to provide the factual and legal basis for its opinion that the '491 Patent is invalid. Because additional defenses to patent infringement may occur, be developed, be uncovered and/or be discovered in the future, Apotex expressly reserves the right to assert additional related and unrelated defenses to patent infringement, in addition to those set forth below, in the event Apotex is sued for patent infringement in the future.

Applicable Law

The United States Patent Statute, 35 U.S.C. § 103(a) provides:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Accordingly, an invention is unpatentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a).

The U.S. Supreme Court recently reaffirmed that the “*Graham* factors” control an obviousness inquiry. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). These factors are (1) “the scope and content of the prior art”; (2) the “differences between the prior art and the claims”; (3) “the level of ordinary skill in the pertinent art”; and (4) objective evidence of nonobviousness. *Id.*, 127 S. Ct. at 1734 (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 at 17-18 (1966)).

The prior art includes printed publications that had “been disseminated or otherwise made available” to those persons interested and of ordinary skill in the art. *Massachusetts Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985). Such printed publications include articles that appeared in scientific journals published prior to the filing date of the relevant patent. *Loral Fairchild Corp. v. Matsushita Elec. Indus. Co., Ltd.*, 266 F.3d 1358, 1360-61 (Fed. Cir. 2001). When a journal article was published more than one year before the earliest effective filing date of the relevant patent, the article presents a statutory bar to patentability. *In re Schoenwald*, 964 F.2d 1122, 1122-23 (Fed. Cir. 1992). This statutory bar applies even when the article is one of a combination of references that collectively render the claimed invention obvious, where each of those references has a publication date more than a year before the filing date of the relevant patent. *In re Foster*, 343 F.2d 980, 988-89 (C.C.P.A. 1965). In this case, even though the US patent claims priority to the French priority document, the Section 102 prior art date is still one year before the US filing date; not one year before the French filing date. See, 35 U.S.C. 119.

U.S. Patent No. 4,661,491

The ‘491 patent is entitled “Alfuzosine Compositions and Use.” The ‘491 patent, which claims priority to French patent application 85 07950, filed May 28, 1985, has an earliest effective U.S. filing date of May 27, 1986. Therefore, the “critical date” of the ‘491 patent is May 27, 1985.

The ‘491 patent contains five claims. Claim 1, the only independent claim, reads as follows:

1. A method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling, non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human animal suffering dysuria.

The ‘491 patent also includes four dependent claims, which read as follows:

2. A method according to claim 1 comprising administering alfuzosine hydrochloride.

3. A method according to claim 1 comprising administering from 0.5 to 10 mg of alfuzosine or the corresponding amount of a pharmaceutically acceptable salt thereof.
4. A method according to claim 1 for treating dysuria in patients having bladder neck disease or a neurological disorder.
5. A method according to claim 1 for treating dysuria in male patients having benign hypertrophy of the prostate of alpha-adrenergic origin.

Analysis

Claim 1

As noted above, independent claim 1 recites administering alfuzosin (or a pharmaceutically acceptable salt thereof) in an amount effective to control dysuria (i.e., painful urination).

Several publications prior to the '491 patent's critical date of May 27, 1985 disclose the use of alfuzosin as an α -adrenergic receptors antagonist. For example, an article published in the *British Journal of Pharmacology* in 1984 explicitly describes using alfuzosin to block vascular α -adrenoceptors. See Cavero et al., *Br. J. Pharmacol.*, Vol. 81, "Alfuzosin (SL 77.499), A New Antihypertensive Agent With A Peripheral Site of Action: II. In Vitro Pharmacological Studies," page 4 (1984) ("Cavero"). Similarly, in an abstract published in *Federation Proceedings* in 1984, alfuzosin is described as antihypertensive agent with α -adrenoceptor antagonist properties. See Cavero et al., *Fed. Proc.*, Vol. 43, No. 3, "Alfuzosin, Antihypertensive Agent With α -Adrenoceptor Antagonist Properties," abstract 2627 (1984). Therefore, the use of alfuzosin to block α -adrenergic receptors was known in the art at least as early as 1984.

Additionally, several articles published prior to the '491 patent's critical date of May 27, 1985 teach using α -adrenergic receptor antagonists to treat conditions of the bladder neck or prostate, including treatment for dysuria.

Specifically, an article published in the *Journal of Urology* in 1983 describes using α -adrenergic blockers to treat benign prostatic obstruction. Hedlund et al., *The Journal of Urology*, Vol. 133, "Effects of Prazosin In Patients With Benign Prostatic Obstruction," pages 275-278 (1983) ("Hedlund"). In particular, the article describes using the α -adrenergic blocker prazosin. It is noteworthy that "Cavero," which discloses the use of alfuzosin as an α -adrenergic antagonist, teaches that alfuzosin has similar α -adrenergic blocking properties to prazosin. In light of the prior art teachings to use alfuzosin as an α -adrenergic antagonist, it would clearly have been obvious to one skilled in the art to use alfuzosin as an α -adrenergic blocker for treating prostatic obstruction, as described in Hedlund. This is particularly true in light of the fact the α -adrenergic antagonist used in

Hedlund is prazosin, and Cavero explicitly describes the similar α -adrenergic blocking properties of alfuzosin and prazosin.

Similarly, an article published in *Urological Research* in 1982 describes using α -adrenergic blockers to treat benign prostatic obstruction, and specifically, dysuria. Ronchi et al., *Urological Research*, Vol. 10, No. 3, "Symptomatic Treatment of Benign Prostatic Obstruction With Nicergoline: A Placebo Controlled Clinical Study and Urodynamic Evaluation," pages 131-134 (1982) (Ronchi). Therefore, because it was known that alfuzosin could be used as an α -adrenergic blocker prior to the critical date of the '491 patent, it would have been obvious to one skilled in the art to use alfuzosin as an α -adrenergic blocker to treat patients suffering from dysuria.

Claim 2

As noted above, claim 2 further recites administering alfuzosin hydrochloride. It is well known that converting organic bases into their hydrochlorides is a common way of making them soluble in water. Therefore, it is also well known to prepare pharmaceuticals as hydrochlorides so that they may be quickly absorbed from the gastrointestinal tract. Accordingly, it would have been obvious for one skilled in the art that, when administering alfuzosin for the treatment of prostate conditions, it would be advantageous to administer alfuzosin as the hydrochloride salt.

Claim 3

As noted above, claim 3 recites administering alfuzosin (or a pharmaceutically acceptable salt thereof) in the amount of 0.5 to 10 mg. As discussed above, Cavero explains that alfuzosin has similar α -adrenergic blocking properties to prazosin, and Hedlund teaches to use α -adrenergic blockers to treat prostatic obstruction. Hedlund explicitly describes administering prazosin to treat prostatic obstruction in doses between 0.5 and 10 mg, including 1 mg, 2 mg, and 4 mg doses. Therefore, for same reason the combined disclosures of Cavero and Hedlund rendered obvious the administration of alfuzosin for treating conditions of the prostate (including dysuria), it would have been obvious for one skilled in the art to administer between 0.5 to 10 mg of alfuzosin.

Claim 4

As noted above, claim 4 further recites administering the alfuzosin (or a pharmaceutically acceptable salt thereof) to patients having bladder neck disease or a neurological disorder, which can impede the flow of urine. As discussed above, multiple publications prior to the '491 patent's critical date of May 27, 1985 disclose using alfuzosin as an α -adrenergic blocker, and various references teach using α -adrenergic receptor antagonists to treat conditions of the bladder neck or prostate. More specifically, an article published in the *British Journal of Pharmacology* in 1976 describes using α -adrenergic

blockers to treat urine outflow resistance caused by the bladder neck. See Whitfield et al., *Br. J. Pharmacol.*, Vol. 47, "The Effect of Adrenergic Blocking Drugs On Outflow Resistance," pages 823-827 (1976). Therefore, because it was known that alfuzosin could be used as an α -adrenergic blocker prior to the critical date of the '491 patent, it would have been obvious to one skilled in the art to use alfuzosin as an α -adrenergic blocker to treat patients with bladder neck disease.

Claim 5

As noted above, claim 5 further recites administering the alfuzosin (or a pharmaceutically acceptable salt thereof) to patients having benign hypertrophy of the prostate of alpha-adrenergic origin (also referred to as benign prostatic obstruction), in which the prostate becomes enlarged and obstructs the flow of urine. As discussed above, multiple publications prior to the '491 patent's critical date of May 27, 1985 disclose using alfuzosin as an α -adrenergic blocker, and various references teach using α -adrenergic receptor antagonists to treat conditions of the bladder neck or prostate. Both Hedlund and Ronchi explicitly teach using α -adrenergic receptor antagonists to treat benign prostatic obstruction. Therefore, because it was known that alfuzosin could be used as an α -adrenergic blocker prior to the critical date of the '491 patent, it would have been obvious to one skilled in the art to use alfuzosin as an α -adrenergic blocker to treat patients with benign prostatic obstruction.

Apotex certifies pursuant to 21 C.F.R. § 314.95(c)(7) that:

Tammy McIntire
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FL 33326

Is hereby authorized to accept service of process on behalf of Apotex in connection with its ANDA No. 79-013 relating to alfuzosin hydrochloride extended release tablets.

Offer of Confidential Access to Application Pursuant to 21 U.S.C § 355(j)(5)(c)

As this Para. IV Notice Letter discusses invalidity only, the provisions for the Offer of Confidential Access do not necessarily apply as the contents of the ANDA have zero bearing on the question of patent invalidity. However, Apotex offers to provide confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(c)(i)(III) can be brought.

21 U.S.C. § 355(j)(5)(c)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a

protective order been entered for the purpose of protecting trade secrets and other confidential business information.” That provision also grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential access:

1. Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in any patent prosecution for you or any FDA counseling, litigation or other work before or involving FDA. Such information (hereinafter, “Confidential Apotex Information”) shall be marked “CONFIDENTIAL”.
2. The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without our prior written consent.
3. As provided by § 355(j)(5)(c)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. Your outside law firm agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Information, and that all Confidential Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.
4. The Confidential Information disclosed is, and remains, the property of Apotex.
5. By providing the Confidential Information, Apotex does not grant your outside law firm any interest in or license for the Confidential Information. Your outside law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Information, return to Apotex, all Confidential Information and any copies thereof. Your outside law firm shall return all Confidential Information to Apotex before any infringement suit is filed by you. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Information that Apotex provides shall be included in any publicly-available complaint or other pleading.
6. Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance or materiality of

any such Confidential Information, document, or thing. The fact that Apotex provides Confidential Information upon your request shall not be construed as an admission by Apotex that such Confidential Information is relevant to the disposition or any issue relating to any alleged infringement of any patent, or to the validity or enforceability of any patent.

7. The attorneys from your outside law firm shall acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Information.

Section 355(j)(5)(C)(i)(III) further provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access," and that the "restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that you request access to Confidential Apotex Information, you mandatorily accept the terms and restrictions attached hereto. Written notice requesting access under this Offer of Confidential Access should be made to:

Bernice Tao
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Reservation of Legal Rights

Apotex reserves the right to allege the same, similar, different or new theories of non-infringement, invalidity, and/or unenforceability, and nothing in the Notice Letter or Detailed Statement shall be construed as to limit Apotex's rights to make any allegation in any subsequent litigation regarding any issue.

Further, please be advised that Apotex considers this information to be confidential, is disclosing this information solely in order to comply with 21 U.S.C. § 355(j)(2)(B), and requests that the recipients of this information protect it from disclosure to third parties by means consistent with their own standards for protecting their own confidential information.

THIS CONFIDENTIALITY APPLIES TO THIS LETTER, WHICH MAY NOT, AND SHOULD NOT, BE ATTACHED TO ANY COMPLAINT OR OTHER PUBLICLY AVAILABLE DOCUMENT. SIMILARLY, THE INFORMATION CONTAINED IN THIS DOCUMENT MAY NOT, AND SHOULD NOT, BE INCLUDED IN ANY COMPLAINT OR OTHER PUBLICLY AVAILABLE DOCUMENT.

* * *

Whereas service of process for Apotex Corp. is based on the Weston, Florida address indicated above, as a professional courtesy, please also copy any service of process to:

Shashank Upadhye, Esq.
Vice President – Global Intellectual Property
150 Signet Drive
Toronto, ON, CANADA
M9L 1T9

Yours very truly,
APOTEX INC.

A handwritten signature in black ink, appearing to be 'B. Sherman', written in a cursive style.

Bernard C. Sherman, PhD., P.Eng.
Chairman and C.E.O.

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

ACTAVIS SOUTH ATLANTIC LLC,
AUROBINDO PHARMA LTD.,
AUROBINDO PHARMA USA INC.,
MYLAN PHARMACEUTICALS INC., PAR
PHARMACEUTICAL, INC., RANBAXY
INC., RANBAXY LABORATORIES
LIMITED, SUN PHARMACEUTICAL
INDUSTRIES, INC., SUN
PHARMACEUTICAL INDUSTRIES LTD,
TEVA PHARMACEUTICALS USA, INC.,
TORRENT PHARMA INC. and TORRENT
PHARMACEUTICALS LIMITED,

Defendants.

C.A. No. - 07 - 57
FILED
U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2007 SEP 21 PM 4:02

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd. ("Aurobindo Ltd."), Aurobindo Pharma USA Inc. ("Aurobindo Inc."), Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc. ("Par"), Ranbaxy Inc., Ranbaxy Laboratories Limited ("Ranbaxy Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva"), Torrent Pharma Inc. ("Torrent Inc.") and Torrent Pharmaceuticals Ltd. ("Torrent Ltd."), hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.
2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
3. Upon information and belief, Defendant Actavis is a Delaware limited liability company having a place of business at 13800 NW 2nd Street, Ste-190, Fort Lauderdale, Florida 33325.
4. Upon information and belief, Defendant Aurobindo Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.
5. Upon information and belief, Defendant Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Aurobindo Inc.
6. Upon information and belief, Defendant Mylan is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504. Upon information and belief, Defendant Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.
7. Upon information and belief, Defendant Par is a Delaware corporation having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

8. Upon information and belief, Defendant Ranbaxy Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Ranbaxy Ltd., having a place of business at 600 College Road East, Princeton, New Jersey 08540.

9. Upon information and belief, Defendant Ranbaxy Ltd. is an Indian corporation having a place of business at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Upon information and belief, Defendant Ranbaxy Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Ranbaxy Inc.

10. Upon information and belief, Defendant Sun Inc. was a Michigan corporation, and the wholly-owned subsidiary and agent of Defendant Sun Ltd., having a place of business at 29714 Orion CT, Farmington Hills, Michigan 48334 at the time it submitted its Abbreviated New Drug Application. Upon information and belief, Sun Inc. dissolved as a corporation on or about July 15, 2007. Upon information and belief, Defendant Sun Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

11. Upon information and belief, Defendant Sun Ltd. is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun Ltd., itself and through its wholly-owned subsidiary and agent Defendant Sun Inc., manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Teva is a Delaware corporation having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

13. Upon information and belief, Defendant Torrent Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Torrent Ltd., having a place of business at 3585 Bellflower Drive, Portage, Michigan 49024.

14. Upon information and belief, Defendant Torrent Ltd. is an Indian company having a place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India. Upon information and belief, Defendant Torrent Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Torrent Inc.

Nature of the Action

15. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940 patent") (Exhibit B). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

18. This Court has personal jurisdiction over Defendant Actavis by virtue of the fact that, *inter alia*, Actavis is a Delaware limited liability company.

19. This Court has personal jurisdiction over Defendant Aurobindo Inc. by virtue of the fact that, *inter alia*, Aurobindo Inc. is a Delaware corporation.

20. This Court has personal jurisdiction over Defendant Aurobindo Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Aurobindo Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Aurobindo Inc.

21. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

22. This Court has personal jurisdiction over Defendant Par by virtue of the fact that, *inter alia*, Par is a Delaware corporation.

23. This Court has personal jurisdiction over Defendant Ranbaxy Inc. by virtue of the fact that, *inter alia*, Ranbaxy Inc. is a Delaware corporation.

24. This Court has personal jurisdiction over Defendant Ranbaxy Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Ranbaxy Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Ranbaxy Inc.

25. This Court has personal jurisdiction over Defendant Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

26. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Sun Inc.

27. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.

28. This Court has personal jurisdiction over Defendant Torrent Inc. by virtue of the fact that, *inter alia*, Torrent Inc. is a Delaware corporation.

29. This Court has personal jurisdiction over Defendant Torrent Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Torrent Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Torrent Inc.

30. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents

31. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

32. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral®.

Acts Giving Rise to this Action

Count I – Infringement of the ‘491 Patent by Defendants Actavis and Par

33. Upon information and belief, Actavis submitted Abbreviated New Drug Application (“ANDA”) 79-055 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis’ Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the ‘491 patent.

34. Actavis alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ‘491 patent are invalid. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

35. Actavis’ submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘491 patent under 35 U.S.C. § 271(e)(2)(A). Actavis’ commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis’ Uroxatral® brand product would infringe the ‘491 patent.

36. Par is jointly and severally liable for Actavis’ infringement of the ‘491 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or induced Actavis’ submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

37. Par’s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the ‘491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Par’s

commercial manufacture, use, offer for sale or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

38. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '491 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

39. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Infringement of the '940 Patent by Defendants Actavis and Par

40. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

41. Actavis has alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

42. Actavis' submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

43. Par is jointly and severally liable for Actavis' infringement of the '940 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or

induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

44. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Par's commercial manufacture, use, offer for sale or sale of its proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

45. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '940 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

46. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count III – Infringement of the '491 Patent by Defendants
Aurobindo Ltd. and Aurobindo Inc.**

47. Upon information and belief, Aurobindo Ltd., through its subsidiary and agent Aurobindo Inc., submitted ANDA 79-060 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

48. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

49. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

50. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '491 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

51. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

52. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

53. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count IV – Infringement of the ‘940 Patent by Defendants
Aurobindo Ltd. and Aurobindo Inc.**

54. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

55. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

56. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

57. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '940 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

58. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the

FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

59. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

60. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count V – Infringement of the '491 Patent by Defendant Mylan

61. Upon information and belief, Mylan submitted ANDA 79-014 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

62. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

63. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C.

§ 271(e)(2)(A). Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

64. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '491 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

65. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VI – Infringement of the '940 Patent by Defendant Mylan

66. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

67. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

68. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Mylan has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-014. However, given Mylan's claim of bioequivalence contained within ANDA 79-014, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation

or discovery that will demonstrate that Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

69. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '940 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

70. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VII – Infringement of the '940 Patent by Defendants
Ranbaxy Ltd. and Ranbaxy Inc.**

71. Upon information and belief, Ranbaxy Ltd., through its subsidiary and agent Ranbaxy Inc., submitted ANDA 79-006 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-006 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

72. Ranbaxy Ltd. alleged in ANDA 79-006 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-006 on or about August 14, 2007.

73. Ranbaxy Ltd.'s submission of ANDA 79-006 to the FDA, through Ranbaxy Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the

'940 patent under 35 U.S.C. § 271(e)(2)(A). Ranbaxy Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

74. Ranbaxy Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Ranbaxy Inc. participated in, contributed to, aided, abetted and/or induced Ranbaxy Ltd.'s submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

75. Ranbaxy Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Ranbaxy Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

76. This is an exceptional case under 35 U.S.C. § 285 because Ranbaxy Ltd. and Ranbaxy Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-006 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

77. Plaintiffs will be irreparably harmed by Defendant Ranbaxy Ltd.'s and Defendant Ranbaxy Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VIII – Infringement of the '940 Patent by Defendants Sun Inc. and Sun Ltd.

78. Upon information and belief, Sun Inc. acting as a subsidiary and agent of Sun Ltd., submitted ANDA 79-057 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 79-057 seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of

alfuzosin hydrochloride per tablet. ANDA 79-057 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

79. Sun Inc. alleged in ANDA 79-057 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-057 on or about September 6, 2007.

80. Sun Inc.'s submission of ANDA 79-057 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Inc. has provided no information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-057. However, given Sun Inc.'s claim of bioequivalence contained within ANDA 79-057, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that will demonstrate that Sun Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

81. Sun Ltd. is jointly and severally liable for Sun Inc.'s infringement of the '940 patent. Upon information and belief, Sun Ltd. participated in, contributed to, aided, abetted and/or induced Sun Inc.'s submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

82. Sun Ltd.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Ltd.'s

commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

83. This is an exceptional case under 35 U.S.C. § 285 because Sun Inc. and Sun Ltd. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-057 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

84. Plaintiffs will be irreparably harmed by Defendant Sun Inc.'s and Defendant Sun Ltd.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count IX – Infringement of the '491 Patent by Defendant Teva

85. Upon information and belief, Teva submitted ANDA 79-056 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended-release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

86. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

87. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C.

§ 271(e)(2)(A). Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

88. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '491 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

89. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count X – Infringement of the '940 Patent by Defendant Teva

90. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

91. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

92. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Teva has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-056. However, given Teva's claim of bioequivalence contained within ANDA 79-056, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or

discovery that will demonstrate that Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

93. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '940 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

94. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count XI – Infringement of the '491 Patent by Defendants Torrent Ltd. and Torrent Inc.

95. Upon information and belief, Torrent Ltd., through its subsidiary and agent Torrent Inc., submitted ANDA 79-054 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

96. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

97. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its

proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

98. Torrent Inc. is jointly and severally liable for any infringement of the '491 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced Torrent Ltd.'s submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

99. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

100. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

101. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count XII – Infringement of the '940 Patent by Defendants Torrent Ltd. and Torrent Inc.

102. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

103. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid and not

infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

104. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

105. Torrent Inc. is jointly and severally liable for Torrent Ltd.'s infringement of the '940 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

106. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

107. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

108. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

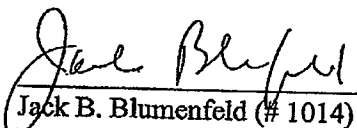
Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Inc. and Torrent Ltd. have infringed the '491 patent;
- B. That all Defendants have infringed the '940 patent;
- C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs identified in this Complaint shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;
- D. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Ltd. and Torrent Inc., their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;
- E. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;
- F. That this case is exceptional under 35 U.S.C. § 285;
- G. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

H. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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Dated: September 21, 2007

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS)
U.S. LLC,)

Plaintiffs,)

v.)

BARR LABORATORIES, INC.,)

Defendant.)

C.A. No. - 07 - 574 -

FILED
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2007 SEP 21 PM 4:06

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendant Barr Laboratories, Inc. ("Barr"), hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174, avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Barr is a Delaware corporation having a place of business at 2 Quaker Road, Pomona, New York 10970.

Nature of the Action

4. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940

patent”) (Exhibit B). This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant Barr by virtue of the fact that, *inter alia*, Barr is a Delaware corporation.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents

8. On April 28, 1987, the ‘491 patent, titled “Alfuzosine Compositions and Use,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”). Plaintiff sanofi-aventis is the current assignee of the ‘491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application (“NDA”) No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The ‘491 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for Uroxatral®.

9. On November 21, 2000, the ‘940 patent, titled “Tablet with Controlled Release of Alfuzosine Chlorhydrate,” was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the ‘940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG’s interests in the ‘940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec

AG has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral®.

Count I – Infringement of the '491 Patent

10. Upon information and belief, Defendant Barr submitted Abbreviated New Drug Application ("ANDA") 79-052 to the United States Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-052 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

11. Barr has alleged in ANDA 79-052 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Sanofi-aventis received written notification of Barr's ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations on or about August 16, 2007.

12. Defendant Barr's submission of ANDA 79-052 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Barr's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

13. This is an exceptional case. Barr was aware of the existence of the '491 patent at the time of the submission of ANDA 79-052 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

14. Plaintiffs will be irreparably harmed by Defendant Barr's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Infringement of the '940 Patent

15. ANDA 79-052 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

16. Barr has alleged in ANDA 79-052 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product. Sanofi-aventis received written notification of Barr's ANDA 79-052 the § 505(j)(2)(A)(vii)(IV) allegations on or about August 16, 2007.

17. Defendant Barr's submission of ANDA 79-052 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Barr's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

18. This is an exceptional case under 35 U.S.C. § 285 because Barr was aware of the existence of the '940 patent at the time of the submission of ANDA 79-052 and its § 505 (j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

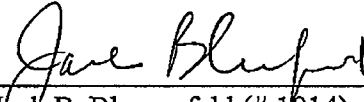
19. Plaintiffs will be irreparably harmed by Defendant Barr's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That Defendant Barr has infringed the '491 patent and the '940 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Barr's ANDA 79-052 shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;
- C. That Defendant Barr, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling its proposed generic version of sanofi-aventis' Uroxatral® brand product, and any other product that infringes or induces or contributes to the infringement of the '491 patent or the '940 patent, prior to the expiration of those patents, including any extensions;
- D. That this case is exceptional under 35 U.S.C. § 285;
- E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and
- F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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*Attorneys for Plaintiffs
sanofi-aventis and sanofi-aventis U.S. LLC*

Dated: September 21, 2007

EXHIBIT F

KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

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New York, New York 10022-4611

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212 446-4900

October 1, 2007

By Email

Bernice Tao
Director, Regulatory Affairs US
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9

Re: Notification of Paragraph IV Certification
for Apotex Inc.'s Alfuzosin Hydrochloride Tablets, 10 mg

Dear Ms. Tao:

By letter dated August 14, 2007, Apotex Inc. ("Apotex") indicated that it submitted Abbreviated New Drug Application ("ANDA") 79-013 for alfuzosin hydrochloride extended release tablets, 10 mg, including a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") against U.S. Patent No. 6,149,940 ("the '940 patent"). Apotex further indicated that it intends to engage in the commercial manufacture, use, import, sale and/or offer for sale of the generic 10 mg alfuzosin hydrochloride extended release product defined by ANDA 79-013 before the expiration of the '940 patent.

In compliance with the procedures provided by the Hatch-Waxman Act, we have reviewed Apotex's letter and the portions of ANDA 79-013 provided by Apotex, as well as discussed Apotex's documents and method of manufacturing with you. In connection with this review, we carefully considered, *inter alia*:

- (1) Apotex's representation at page 2 of the August 14th letter that Apotex's proposed alfuzosin hydrochloride tablets "do not comprise two or more layers;" and
- (2) Apotex's representations in the portions of ANDA 79-013 provided regarding the composition of its proposed generic alfuzosin hydrochloride extended release product and the method of manufacturing for that product.

In reliance on Apotex's representations in its letter, the portions of ANDA 79-013 provided and the conversation with you, including the specific representations recited above,

KIRKLAND & ELLIS LLP

Bernice Tao
October 1, 2007
Page 2

sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") will not file an action for infringement of the '940 patent against Apotex at this time. Sanofi-aventis, however, reserve the right to file such an action if they learn that Apotex's representations were incorrect or if Apotex or any other party amends ANDA 79-013.

In this regard, we remind Apotex that it is required to submit to the U.S. Food and Drug Administration an additional certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '940 patent if it amends ANDA 79-013 to change the composition or the method of manufacturing of the generic alfuzosin hydrochloride product defined therein. To the extent that Apotex makes any such certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it must also provide sanofi-aventis with the notice required by 21 U.S.C. § 355(j)(2)(B).

Sincerely,

A handwritten signature in black ink, appearing to read 'W. T. Vuk', with a long horizontal line extending to the right.

William T. Vuk

cc: Dr. Bernard C. Sherman (via Federal Express)

EXHIBIT G

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALLERGAN, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 07-278-GMS
)	
APOTEX, INC. and APOTEX CORP.,)	JURY TRIAL DEMANDED
)	
Defendants.)	

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S ANSWER,
DEFENSES, AND COUNTERCLAIMS.**

Defendants Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the Complaint of Allergan, Inc. ("Allergan" or "Plaintiff"), state and allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2).

ANSWER: Apotex Inc. and Apotex Corp. admit that the Complaint alleges infringement of United States Patents Nos. 5,424,078, ("the '078 patent"), 6,562,873 ("the '873 patent"), 6,627,210 ("the '210 patent"), 6,673,337 ("the '337 patent"), and 6,641,834 ("the '834 patent") under 35 U.S.C. §271(e)(2); otherwise denied.

THE PARTIES

2. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

3. On information and belief, defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER: Admitted that Apotex Inc. is a Canadian corporation with a place of business in Ontario Canada, all other allegations are denied.

4. On information and belief, defendant Apotex, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

ANSWER: Admitted.

5. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

ANSWER: Admitted.

6. On information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States, including this judicial district; otherwise denied.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq. This Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338.

ANSWER: Apotex Inc. and Apotex Corp. admit that Allergan purports to bring this action under the patent laws of the United States, Title 35, Section 1, et seq. Apotex Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the action under 28 U.S.C. §1331 and 1338(a). Except where specifically admitted, the allegations in this paragraph are otherwise denied.

8. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.

ANSWER: Admitted that the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.; otherwise denied.

9. Venue is proper in this Court under 28 U.S.C. §1391 and 1400(b).

ANSWER: Admitted.

BACKGROUND

10. The '078 patent, entitled "Aqueous Ophthalmic Formulations and Methods for Preserving Same," issued to Anthony Dziabo and Paul Ripley on June 13, 1995. A copy of the '078 patent is attached to this complaint as Exhibit A.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the cover page of the '078 patent includes a title of "Aqueous Ophthalmic Formulations and Methods for Preserving Same," lists the inventors as Anthony Dziabo and Paul Ripley, and lists an issue date of June 13, 1995. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the remaining averments in this paragraph, and therefore deny the same.

11. Allergan, Inc., as the assignee, owns the entire right, title, and interest in the '078 patent.

ANSWER: Admitted that in conjunction with NDA No. 21-262 and 21-770, Allergan listed the '078, '873, '210, '337 and '834 patents. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

22. ALPHAGAN® P 0.15% and 0.10% are covered by at least one claim of each of the Listed Patents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore deny the same.

23. On April 30, 2007, Allergan received a letter, dated April 26, 2007, signed on behalf of Apotex, Inc. The letter stated that Apotex had filed Abbreviated New Drug Application Nos. 78-479 and 78-480 ("ANDAs") with the United States Food and Drug Administration ("FDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market generic versions of Allergan's ALPHAGAN® P products, both the 0.15% and 0.10% formulations, before the expiration of the Listed Patents.

ANSWER: Admitted that Apotex Inc. sent a letter to Allergan on April 26, 2007; that the letter stated that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, before the expiration of the listed patents; otherwise denied.

24. The purpose of the April 26, 2007 letter was to notify Allergan that Apotex had filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4) ("Paragraph IV

certification”) in conjunction with its ANDAs. The letter alleged: (1) that the Listed Patents were invalid or unenforceable and (2) that, even if valid and enforceable, some claims of the Listed Patents would not be infringed by Apotex’s generic versions of Allergan’s ALPHAGAN® P products.

ANSWER: Admitted that the April 26, 2007 letter provided Allergan with notice that Apotex Inc. had filed a Paragraph IV certification with the FDA in conjunction with ANDA application nos. 78-479 and 78-480, admitted that the April 26, 2007 letter stated that the listed patents are invalid, unenforceable, and/or will not be infringed by Apotex’s manufacture, use, or sale of the Apotex Brimonidine Products, otherwise denied.

25. In filing its ANDAs, Apotex has requested the FDA’s approval to market generic versions of Allergan’s ALPHAGAN® P products throughout the United States, including Delaware.

ANSWER: Admitted that Apotex Inc. had submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex’s Proposed Products, Brimonidine Tartrate Ophthalmic Solution, 0.15% and Brimonidine Tartrate Ophthalmic Solution, 0.1%, as defined in ANDA applications 78-479 and 78-480, throughout the United States, including Delaware; otherwise denied.

26. On information and belief, following FDA approval of its ANDAs, Apotex, Inc., through Apotex Corp., will sell the approved generic versions of Allergan’s ALPHAGAN® P products throughout the United States, including Delaware.

ANSWER: Admitted that if the FDA approves Apotex Inc.’s ANDA applications, it will seek to sell its approved Brimonidine Tartrate products throughout

the United States, and that it would be expected that such approved products would be sold by Apotex Inc., otherwise denied.

COUNT I

(Infringement of the '078 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

27. Paragraphs 1 to 26 are incorporated herein as set forth above.

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference their answers to Paragraphs 1 to 26 as set forth above.

28. Apotex submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of a proposed 0.15% brimonidine tartrate ophthalmic solution product throughout the United States. By submitting the application, Apotex has committed an act of infringement under 35 U.S.C. §271 (e)(2)(A).

ANSWER: Admitted that Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Product, Brimonidine Tartrate Ophthalmic Solution, 0.15% as defined in ANDA application 78-479. The remainder of the allegations are denied.

29. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product will constitute an act of infringement of the '078 patent.

ANSWER: Denied.

COUNT II

(Infringement of the '873 Patent Under 35 U.S.C. §271(e)(2) by Apotex's proposed generic 0.15% brimonidine tartrate ophthalmic solution product)

products for which approval is sought under ANDA applications 78-479 and 78-480 do not directly or indirectly infringe any valid claim of the '078, '873, '210, '337 and '834 patents.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

- a. Finding that the '078, '873, '210, '377 and '834 patents are invalid and unenforceable;
- b. Finding that the '078, '873, '210, '377 and '834 patents are not infringed in any manner by either Apotex Inc. or Apotex Corp.;
- c. Finding that this is an exceptional case under 35 U.S.C. § 285;
- d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand a trial by jury on all issues appropriately tried to a jury.

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Dated: June 11, 2007
800700 / 31920

POTTER ANDERSON & CORROON LLP

By: /s/ Richard L. Horwitz
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*Attorneys for Defendants
Apotex Inc. and Apotex Corp.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDPOINTE HEALTHCARE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 07-204-SLR
)	
APOTEX INC. and APOTEX CORP.,)	JURY TRIAL DEMANDED
)	
Defendants.)	

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the complaint of MedPointe Healthcare Inc. ("Plaintiff" or "MedPointe"), state and allege as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 1 of the Complaint, and therefore deny same.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admitted.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Admitted.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

ANSWER: Apotex Inc. and Apotex Corp. admit that MedPointe purports to bring an action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, for the alleged infringement of United States Patent No. 5,164,194; otherwise denied.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

ANSWER: Admitted that this Court has personal jurisdiction over Apotex Corp. for this action.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego; (4) its consent to personal jurisdiction in this Court in connection with another action for infringement of the '194 patent, Civil Action No. 06-164-SLR.

ANSWER: Denied, except to admit that this Court has personal jurisdiction over Apotex Inc. for this action.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

ANSWER: Admitted.

THE PATENT

14. On November 17, 1992, the '194 patent, titled "AzelaStine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Apotex Inc. and Apotex Corp. admit that the '194 patent, entitled "AzelaStine Containing Medicaments," was issued by the United States Patent and Trademark Office on November 17, 1992, that Asta Pharma AG is listed as the assignee, and that a document purporting to be a copy of the '194 patent is attached to the Complaint. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of paragraph 14, and therefore deny same. Defendants deny all other allegations in paragraph 14.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about December 13, 2006, Apotex submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on or about December 13, 2006.

16. ANDA 78-621 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic ophthalmic solution product containing 0.05% azelaStine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 78-621 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Denied, except to admit that ANDA 78-621 seeks FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a proposed drug

product as defined in ANDA 78-621 and that ANDA 78-621 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent.

17. ANDA 78-621 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written notification of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation on March 14, 2007.

ANSWER: The first sentence of paragraph 17 of the Complaint is admitted.

With regard to the second sentence in paragraph 17, Apotex Inc. and Apotex Corp. admit that Apotex Inc. sent written notification of ANDA 78-621 to MedPointe on or about March 12, 2007.

18. Upon information and belief, consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the United States for purposes of filing ANDA 78-621 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 78-621.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States following FDA approval. Apotex Inc. and Apotex Corp. further admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

19. Apotex's submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Denied.

20. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

- a. Finding that the '194 patent is invalid and unenforceable;
- b. Finding that the '194 patent is not infringed in any manner by either Apotex Inc. or Apotex Corp.;
- c. Finding that this is an exceptional case under 35 U.S.C. § 285;
- d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand trial by jury for all issues triable by jury.

This demand is contingent upon MedPointe seeking monetary damages as set forth in paragraph D of its prayer for relief in its complaint.

POTTER ANDERSON & CORROON LLP

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Dated: May 30, 2007
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*Counsel for Defendants Apotex Inc. and
Apotex Corp.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDPOINTE HEALTHCARE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 06-164 (SLR)
)	
APOTEX INC. and APOTEX CORP.,)	JURY TRIAL DEMANDED
)	
Defendants.)	

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO
PLAINTIFF'S AMENDED COMPLAINT, AFFIRMATIVE DEFENSES
AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., Answer the Amended Complaint of Plaintiff, MedPointe Healthcare Inc., as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments in this paragraph.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admit that Apotex, Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 380 Elgin Hills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

8. Upon information and belief, Apotex Corp. is the United States subsidiary and alter ego of Apotex Inc. Upon information and belief, for purposes of this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

ANSWER: Deny, except to admit that Apotex Inc. and Apotex Corp. are related companies and that Plaintiff may refer to them collectively as Apotex even though they are separate entities.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*

ANSWER: This paragraph contains MedPointe's characterization of its action and to which no answer is required, but insofar as an answer is required, deny.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admit.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

ANSWER: Admit.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; and (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego.

ANSWER: Deny, except to admit that this Court has personal jurisdiction over Apotex, Inc. for this matter.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

ANSWER: Apotex admits that venue in this district is proper for this action

THE PATENT

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Deny that the '194 patent was duly and legally issued on November 17, 1992. Admit that a document purporting to be U.S. Patent Number 5,164,194 was attached to the Complaint, and that Asta Pharma AG is listed thereon as assignee. With regard to the remaining allegations, Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of these averments, which has the effect of denial reasonably based on lack of information and belief.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about November 14, 2005, Apotex submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Deny, expect to admit that Apotex Inc. submitted ANDA 077954 to the FDA under §505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 335) on or about November 14, 2005.

16. ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal rhinitis ("the Generic Product"). ANDA 77-954 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Admit that ANDA 77-954 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution having the name Azelastine Hydrochloride Nasal Spray (the “proposed product”) for use in treating, *inter alia*, seasonal rhinitis, and that ANDA 77-954 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the ’194 patent. The remaining allegations are denied.

17. ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ’194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written Notification of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation on January 27, 2005.

ANSWER: Admit that ANDA 77-954 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ’194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the proposed drug product. Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining averments, which has the effect of denial reasonably based on lack of information and belief.

18. In the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its “agent in the United States authorized to accept service of process for Apotex.”

ANSWER: Admit that in the written notification of ANDA 77-954, Apotex Inc. designated Apotex Corp. as its “agent in the United States authorized to accept service of process for Apotex.”

19. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the

United States for purposes of filing ANDA 77-954 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 77-954.

ANSWER: Deny, except to admit that Apotex Inc. has designated Apotex Corp. as its agent in the United States in ANDA 77-954 to the extent required by FDA regulations and for service of legal process.

20. Apotex's submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

21. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

ANSWER: Deny.

22. Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. This is so because, upon information and belief, Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and will, *inter alia*, manufacture, offer to sell and sell the Generic Product upon receipt of any FDA approval of ANDA 77-954.

ANSWER: Deny that Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. Admit that Apotex Inc. submitted ANDA 77-954 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and intends to, *inter alia*, manufacture the proposed drug product upon receipt of FDA approval of ANDA 77-954.

23. Apotex Inc.'s submission of ANDA 77-954 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35

U.S.C. §271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Admit that Apotex Inc. submitted ANDA 77-954 to the FDA, including the §505(j)(2)(A)(vii)(IV) allegation. All other averments of this paragraph are denied.

24. Apotex Corp. is jointly and severally liable for the infringement of the '194 patent, regardless of which Apotex entity actually filed ANDA 77-954 and regardless of whether it is treated as the alter ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, offer to sell and sell the Generic Product within the United States and this judicial district upon receipt of any FDA approval of ANDA 77-954.

ANSWER: Deny, except to admit that if ANDA 77-954 is approved, it is expected that Apotex Corp. would offer to sell and sell the proposed drug product in the United States.

25. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 77-954 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271 (e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Deny.

26. Apotex had actual and constructive notice of the '194 patent prior to filing ANDA 77-954.

ANSWER: Deny, except to admit that Apotex Inc. and Apotex Corp. had access to the FDA Orange Book which listed the '194 patent.

27. MedPointe will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. MedPointe does not have an adequate remedy at law.

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Dated: April 14, 2006
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*Attorneys for Defendants
Apotex Inc. and Apotex Corp.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MERCK & CO., INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 06-230 (GMS)
)	
APOTEX, INC.)	JURY TRIAL DEMANDED
)	
Defendant.)	

**DEFENDANT APOTEX, INC.'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant, Apotex, Inc. ("Defendant" or "Apotex"), for its Answer, Affirmative Defenses, and Counterclaim, to the complaint of Merck & Co., Inc. ("Plaintiff" or "Merck"), states and alleges as follows:

THE PARTIES

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in this paragraph, and therefore denies same.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

ANSWER: Apotex admits that Merck purports to bring an action under the patent laws of the United States of America and admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); otherwise denied.

4. Venue is proper in this court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

ANSWER: Admitted.

BACKGROUND

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the “‘941 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘941 patent is currently set to expire on December 2, 2012. The ‘941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant hypercalcemia, and metastatic bone disease. A copy of the ‘941 patent is attached to this Complaint as Exhibit 1.

ANSWER: Apotex admits that United States Patent No. 5,358,941, entitled “Dry Mix Formulation For Bisphosphonic Acids With Lactose” was issued by the United States Patent and Trademark Office on October 25, 1994 to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare, and that a copy of the ‘941 patent is attached to the complaint. Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of this paragraph, and therefore denies same. Apotex denies all other allegations in this paragraph.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the “‘590 patent”), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The ‘590 patent is currently set to expire on December 2, 2012. The ‘590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget’s disease, malignant hypercalcemia, and metastatic bone disease. A copy of the ‘590 patent is attached to this Complaint as Exhibit 2.

pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX[®] tablets until six months after the expiration date of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX[®] tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

ANSWER: Apotex admits that the Orange Book shows the pediatric exclusivity period for the patents as stated in the averments in this paragraph and Apotex denies the remaining averments in this paragraph.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

ANSWER: Admitted.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX[®] pharmaceutical products have created due to their benefits and advantages.

ANSWER: Denied, except to admit that Apotex seeks permission from the FDA to sell a generic version of Fosamax[®].

COUNT I

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

ANSWER: Apotex incorporates the answers to paragraphs 1 to 18 above, as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

I hereby certify that on May 9, 2006, I have Federal Expressed the attached document to
the following non-registered participants:

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728942

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TORPHARM, INC., APOTEX CORP.,
and APOTEX, INC.

Plaintiffs,

v.

PFIZER INC., and WARNER-
LAMBERT COMPANY (n/k/a
WARNER-LAMBERT LLC)

Defendants.

Civil Action No. 03 - 990

COMPLAINT FOR DECLARATORY JUDGMENT
AND DEMAND FOR JURY TRIAL

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc. (collectively "TorPharm"), for their Complaint against Defendants Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) (collectively "Pfizer"), allege as follows:

Nature Of The Action

1. This action for declaratory judgment of patent noninfringement arises, *inter alia*, out of TorPharm's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's blockbuster drug Accupril® (quinapril hydrochloride). FDA approval of TorPharm's ANDA is imminent.
2. Pfizer owns U.S. Patent No. 4,743,450 ("the '450 patent"), which discloses and claims, *inter alia*, a quinapril pharmaceutical composition. Pfizer has listed the '450 patent in the FDA's "Orange Book" and, as a consequence, maintains that the '450 patent claims the approved drug, Accupril® (quinapril hydrochloride), and that a claim for patent infringement

could reasonably be asserted against any ANDA applicant attempting to market a generic quinapril product. Pfizer, moreover, has enforced and continues to vigorously enforce its intellectual property rights on blockbuster drugs against TorPharm and others, and has already sued and obtained a judgment of infringement on the '450 patent against another generic quinapril applicant.

3. TorPharm has designed around the '450 patent with its proposed quinapril product and so, as required by statute, has certified to the FDA that its product will not infringe the '450 patent and further notified Pfizer of the legal and factual bases for that certification. TorPharm's certification to the '450 patent constitutes a technical or artificial act of infringement under the Hatch-Waxman Act putting TorPharm at considerable risk of being sued by Pfizer both before and after market entry. Pfizer has not yet responded to the submission of TorPharm's ANDA and certification that TorPharm does not infringe. Moreover, Pfizer has not informed TorPharm that TorPharm does not infringe the '450 patent and has not covenanted not to sue TorPharm for infringement of the '450 patent.

4. On information and belief, Pfizer believes that a claim for infringement could be reasonably asserted against TorPharm and Pfizer intends to sue TorPharm for infringement of the '450 patent. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent, for which this Court can declare the rights of the parties. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril product does not and will not infringe the '450 patent.

The Parties

5. Plaintiff TorPharm, Inc. is a corporation duly organized and existing under the laws of Canada and having its principal place of business in Etobicoke, Ontario, Canada. TorPharm develops, manufactures and markets generic drugs, and in particular solid oral dosage forms such as capsules and tablets, for sale and use in the United States following FDA approval.

6. Plaintiff Apotex Corp. is a corporation incorporated and existing under the laws of the State of Delaware, having a place of business at 616 Heathrow Drive, Lincolnshire, Illinois 60069. Apotex Corp. is the United States marketing and sales affiliate for TorPharm. Following FDA approval of an ANDA, TorPharm manufactures and supplies generic drug products to Apotex Corp., which then markets and sells those products to large wholesalers, warehousing chains, mail order organizations, and distributors in the United States. Apotex Corp. also acts as TorPharm's U.S. agent for purposes of making regulatory submissions, including ANDAs, to the FDA.

7. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada and having its principal place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

8. Plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. are collectively referred to in this Complaint as "TorPharm."

9. On information and belief, Defendant Pfizer Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017-5575.

10. On information and belief, Defendant Warner-Lambert Company was or is a Delaware corporation with a place of business at 201 Tabor Road, Morris Plains, New Jersey 07950. On information and belief, Warner-Lambert Company became a wholly-owned

subsidiary of Pfizer Inc. as of June 19, 2000. On information and belief, Warner-Lambert Company subsequently became Warner-Lambert LLC, a limited liability company incorporated under the laws of the State of Delaware, having its principal place of business at 201 Tabor Road, Morris Plains, New Jersey 07950.

11. Defendants Pfizer Inc. and Warner-Lambert Company are collectively referred to in this Complaint as "Pfizer."

Jurisdiction And Venue

12. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

14. There exists a substantial and continuing actual, justiciable case or controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

15. This Court may declare the rights and legal relations of the parties regarding noninfringement of the '450 patent pursuant to, *inter alia*, 28 U.S.C. §§ 2201, 2202.

16. This Court has personal jurisdiction over Pfizer Inc. and Warner-Lambert Company (n/k/a Warner-Lambert LLC) because they both reside and are located in this District and because they both conduct substantial business in, and have regular and systematic contact with, this District.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Statutory Scheme For Approval Of New And Generic Drugs

18. The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman").

New drugs and patent listing requirements

19. Before marketing an original new drug (*i.e.*, not a generic drug) in the United States, Hatch-Waxman requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

20. An NDA applicant is required, within its NDA, to submit information (*i.e.*, *inter alia*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1).

21. FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

22. By filing an NDA and listing a patent in the Orange Book, the NDA-holder and/or patentee, by law, necessarily maintains that the listed patent claims the approved NDA drug and

that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, sale or use of the drug.

23. In other words, the NDA-holder and/or patentee necessarily puts all prospective generic ANDA-filers on notice that a suit for infringement can and will be asserted against any ANDA-filer that attempts to seek approval for and market a generic version of the NDA drug.

24. Such conduct by the NDA-bolder and/or patentee gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit or the threat of one if it attempts to seek approval for or to market a generic version of the NDA drug.

Generic drugs and patent certification requirements

25. Hatch-Waxman provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-cost generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

26. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already approved NDA drug by submitting an ANDA to the FDA under 21 U.S.C. § 355(j).

27. Instead of repeating the comprehensive, extensive human studies conducted for the previously approved NDA drug, a generic applicant submitting an ANDA is only required to establish, among other details, that its proposed generic product is bioequivalent to the already approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption) and that

it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

28. An ANDA applicant is also required to address each patent listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each listed patent: (I) that the NDA-holder has not submitted any patent information to FDA; (II) that the listed patent(s) has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent.

29. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder and the patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal basis for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(ii).

30. The submission of a paragraph IV certification for a listed patent constitutes an artificial or technical act of infringement that creates the necessary subject matter jurisdiction to enable a patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

31. Upon receipt of the notice of the paragraph IV certification for the listed patent submitted by the ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within forty-five (45) days of receiving such notification.

32. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of generic drug products.

33. Congress intended that the generic manufacture and marketing of a drug should be allowed as soon as it is determined that the particular drug does not violate patent rights, and should not be delayed just because the patentee has not sued the generic applicant first, but rather has merely held its patents over the generic applicant like a modern-day “Sword of Damocles.”

34. Congress therefore contemplated that ANDA-filers must obtain a favorable court decision on the patent in order to market the generic drug. This can be accomplished by either being sued by the NDA-holder/patentee within the 45-day period or by the generic ANDA-filer seeking a declaratory judgment of patent infringement and/or invalidity.

35. An ANDA-filer is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder may bring suit after receiving notification of the ANDA and paragraph IV certification. Congress, however, clearly intended that a

declaratory judgment action be available for ANDA-filers who are not sued by the NDA patentee within the 45-day period.

36. The acts of an NDA-holder/patentee listing a patent in the Orange Book through the filing of an NDA and a generic manufacturer filing an ANDA together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement and/or invalidity.

Pfizer's Accupril® (Quinapril Hydrochloride)

37. On information and belief, Pfizer Inc. is the holder of approved NDA No. 19-885 for quinapril hydrochloride tablets, which are sold under the brand-name Accupril®.

38. Accupril® (quinapril hydrochloride) is indicated for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

39. On information and belief, Warner-Lambert Company purports and claims to be the owner of U.S. Patent No. 4,743,450 ("the '450 patent"), the term of which expires on or about August 24, 2007. The '450 patent recites a quinapril pharmaceutical formulation containing a metal-containing stabilizer and a saccharide which minimize the cyclization, hydrolysis and coloration of certain ACE inhibitors, including quinapril. A true and correct copy of the '450 patent is attached to this Complaint as Exhibit A.

40. On information and belief, Pfizer purports and claims to have the right to enforce the '450 patent.

41. Pfizer submitted information on the '450 patent to FDA for placement in the Orange Book. By virtue of that submission, the FDA listed the '450 patent in the Orange Book in connection with Pfizer's approved NDA for Accupril® (quinapril hydrochloride) tablets.

42. By listing the '450 patent in the Orange Book, Pfizer maintains that the '450 patent claims Accupril® (quinapril hydrochloride) tablets and that an infringement suit could reasonably be asserted against any generic ANDA-filer that attempts to seek approval for and market a generic version of quinapril.

TorPharm's ANDA For Quinapril Hydrochloride Tablets

43. On September 13, 2001, TorPharm submitted an ANDA to the FDA seeking approval to market a generic version of Accupril® (quinapril hydrochloride) tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths. That ANDA was received by the FDA on September 20, 2001 and was assigned ANDA number 76-240 by the FDA ("ANDA No. 76-240").

44. TorPharm's ANDA sought permission to market quinapril hydrochloride tablets for the treatment of hypertension and as adjunctive therapy in the management of heart failure.

45. As part of its ANDA No. 76-240, TorPharm submitted a paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifying to FDA that the '450 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

46. On information and belief, the FDA's review of TorPharm's ANDA No. 76-240 will be completed in the near future and approval is imminent.

47. TorPharm intends and is prepared to market its generic quinapril product before expiration of the '450 patent.

48. On or about November 15, 2001, in accordance with 21 U.S.C. §§ 355(j)(2)(B)(i),(ii), TorPharm provided Pfizer with notice that it submitted a quinapril ANDA and a paragraph IV certification to the '450 patent. This notice included a detailed statement setting forth the factual and legal bases why the '450 patent will not be infringed by the

manufacture, use, offer for sale, sale, or importation of TorPharm's quinapril hydrochloride tablets.

**Pfizer's Litigious Conduct And Vigorous Enforcement
Of Its Intellectual Property Rights**

49. Pfizer has a long history and program of vigorously enforcing its patents against generic drug applicants, including TorPharm.

50. For example, Pfizer (and its predecessors) have sued numerous ANDA-filers for alleged infringement of patents covering its blockbuster drug Zoloft[®]. (*Pfizer v. Zenith Goldline Pharms., Inc.*, 00-CV-0408 (D.N.J.)).

51. Pfizer (and its predecessors) have also sued ANDA-filers for alleged infringement of patents covering its blockbuster drug Norvasc[®]. (*Pfizer v. Dr. Reddy's Labs.*, 02-CV-2829 (D.N.J.)).

52. Pfizer (and its predecessors) also filed suit against a generic competitor regarding Pfizer's drug Procardia XL[®] (nifedipine). (*Bayer AG, et al. v. Mylan Labs.*, 97-CV-1309 (W.D. Pa.)).

53. Similarly, Pfizer (and its predecessors) have sued ANDA-filers for alleged infringement of patents covering Pfizer's drug Glucotrol XL[®] (glipizide). (*Pfizer Inc. v. Andrx Corp.*, 01-CV-3260 (D.N.J.)).

54. Pfizer (and its predecessors) also sought to protect its drug Diflucan[®] (fluconazole) from generic competition by filing suit against ANDA-filers. (*Pfizer Inc. v. Novopharm Ltd.*, 00-CV-1475 (N.D. Ill.)).

55. Pfizer (and its predecessors) have further sued at least eight ANDA-filers, including TorPharm, in numerous Districts for alleged infringement of three patents purportedly covering Pfizer's drug Neurontin[®] (gabapentin). (*In re Gabapentin Patent Litig.*, MDL No. 1384

(D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 01-CV-611 (D.N.J.); *Pfizer Inc. v. Apotex Corp.*, 00-CV-4398 (N.D. Ill.); *Warner-Lambert Co. v. Apotex Corp.*, 98-CV-4293 (N.D. Ill.); *Pfizer Inc. v. Pharm. Holdings Corp.*, 03-CV-740 (E.D. Pa.); *Pfizer Inc. v. Geneva Pharms., Inc.*, 03-CV-1545 (D.N.J.); *Pfizer Inc. v. Ranbaxy Pharms., Inc.*, 03-CV-1824 (D.N.J.)).

56. Indeed, as recently as October 7, 2003, Pfizer stated that it intends to aggressively defend its intellectual property. *Found at* http://www.pfizer.com/arc/news_releases.

Quinapril Hydrochloride Litigation

57. Pfizer has further demonstrated a willingness and intention to enforce the '450 patent against similarly-situated generic pharmaceutical companies that have filed an ANDA to market generic quinapril hydrochloride.

58. Pfizer has filed suit against one of TorPharm's competitors in *Warner-Lambert v. Teva Pharms. USA, Inc.*, 99-CV-0922 (D.N.J.), alleging infringement of the '450 patent. The district court in New Jersey recently granted Pfizer a summary judgment of infringement against Teva regarding the '450 patent.

59. Pfizer recently noted that the court decision on the '450 patent "affirms positions that [Pfizer] has taken with respect to the Accupril patent from the very beginning of the litigation." *Found at* http://www.pfizer.com/arc/news_releases.

There Is A Substantial And Continuing Justiciable Controversy Between TorPharm And Pfizer Regarding Infringement Of The '450 Patent

60. By preparing and filing TorPharm's ANDA No. 76-240, TorPharm has substantially prepared to make, use, import, offer to sell, and sell quinapril hydrochloride tablets in the United States.

61. By submitting its ANDA No. 76-240 to engage in the commercial manufacture, use, offer for sale, sale, or importation of quinapril hydrochloride tablets before the expiration of

the '450 patent, as well as filing a paragraph IV certification to the '450 patent, TorPharm has committed an act that may be viewed as an artificial or technical act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2)(A).

62. By submitting the '450 patent to the FDA for listing in the Orange Book, Pfizer has indicated that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." See 21 U.S.C. § 355(b)(1). In other words, Pfizer necessarily maintains that an infringement claim on the '450 patent could be reasonably asserted against any generic quinapril applicant, including TorPharm.

63. Pfizer did not sue TorPharm for infringement of the '450 patent within forty-five (45) days of receipt of TorPharm's notice of paragraph IV certification. As such, a declaratory judgment action is available to TorPharm.

64. Pfizer has never communicated to TorPharm that TorPharm does not infringe or that Pfizer does not intend to bring a lawsuit against TorPharm for infringement of the '450 patent.

65. Pfizer has demonstrated a willingness and, further, an intention to enforce its '450 patent against similarly situated quinapril hydrochloride ANDA-filers. Also, just three weeks ago and after a favorable summary judgment award regarding the '450 patent, Pfizer made public representations that the decision is in line with Pfizer's beliefs regarding Accupril® (quinapril hydrochloride) and that Pfizer intends to continue aggressively defending its intellectual property.

66. Based upon, *inter alia*, Pfizer's listing of the '450 patent and implicit assertions that an infringement claim could be brought against any generic quinapril applicant; TorPharm's ANDA with a paragraph IV certification to the '450 patent and technical or artificial act of

infringement; TorPharm's intention to market its generic quinapril product before expiration of the '450 patent; Pfizer's failure to state that TorPharm does not infringe the '450 patent or covenant that it will not sue TorPharm for infringement of the '450 patent; Pfizer's suits against similarly situated third-parties concerning the '450 patent; Pfizer's public statements that it will continue to aggressively defend challenges to its intellectual property; Pfizer's (and its predecessors') pattern of aggressively enforcing its patents against TorPharm specifically and the generic pharmaceutical industry generally; and Pfizer's recent summary judgment of infringement regarding the '450 patent, TorPharm is under a reasonable apprehension that Pfizer will sue TorPharm alleging infringement of the '450 patent. Such a reasonable apprehension creates an actual controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

67. To avoid legal uncertainty, to protect its substantial investment, and to protect its anticipated future investments in its manufacturing process for TorPharm's quinapril hydrochloride tablets, TorPharm has instituted this action and is entitled to a declaration of the rights of the parties with respect to the '450 patent.

Declaratory Judgment Of Noninfringement

68. TorPharm asserts and realleges paragraphs 1 through 67 above as if fully set forth herein.

69. TorPharm has already committed what may constitute a technical or artificial act of infringement by submitting its ANDA with an accompanying paragraph IV certification. TorPharm has also produced an allegedly infringing quinapril product and intends and is prepared to market that product before expiration of the '450 patent.

70. Pfizer has engaged, and continues to engage, in conduct giving rise to a reasonable and objective apprehension on TorPharm's part that TorPharm will face an infringement suit if it commences marketing of its generic quinapril product.

71. There is an actual, substantial, and continuing justiciable case and controversy between TorPharm and Pfizer regarding infringement of the '450 patent.

72. The manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

73. TorPharm is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent.

Prayer For Relief

WHEREFORE, TorPharm respectfully prays for judgment in its favor and against Pfizer:

- (a) Declaring that the manufacture, sale, offer for sale, use, or importation of TorPharm's proposed quinapril drug product, that is the subject of ANDA No. 76-240, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '450 patent; and
- (b) Awarding TorPharm its reasonable attorneys' fees and costs of this action; and,

- (c) Awarding TorPharm such other and further relief as the Court may deem just and proper.

Jury Demand

The Plaintiffs, TorPharm, Inc., Apotex Corp., and Apotex, Inc., hereby demand a trial by jury on all issues so triable.

ASHBY & GEDDES



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Dated: October 29, 2003
134300.1

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December 6, 2007

By Federal Express
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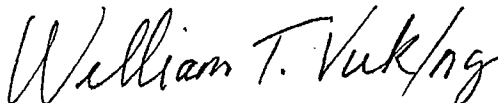
Re: Apotex Inc.'s ANDA 79-013

Dear Dr. Sherman and Ms. McIntyre:

Enclosed are (1) a courtesy copy of the Complaint filed today by sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") against Apotex Inc. and Apotex Corp. (collectively "Apotex") in the United States District Court for the District of Delaware, and (2) copies of two Complaints from related cases previously filed by sanofi-aventis in the District of Delaware with respect to other generic challengers of Uroxatral®.

Please let me know by noon on Monday December 10, 2007 if Apotex will consent to jurisdiction in Delaware.

Sincerely,


William T. Vuk

enclosures

cc by email:

Bernice Tao (btao@apotex.com)
Apotex Inc.

Jack Blumenfeld, Esq.
Morris Nichols Arsht & Tunnell

EXHIBIT I

From: Noreika, Maryellen
Sent: Tuesday, December 11, 2007 4:30 PM
To: 'srollo@welshkatz.com'
Subject: sanofi v. Apotex

Dear Sherry --

This will confirm our earlier discussion that 1) the Apotex defendants will not contest jurisdiction in the District of Delaware in the litigation -- *sanofi-aventis, et al. v. Apotex Inc., et al.*, C.A. No. 07-792 (D. Del) -- and 2) plaintiffs will consent to Apotex's request for a 14 day extension to respond to the complaint. I will draft a stipulation regarding the extension for your review.

Maryellen Noreika

This message, including any accompanying documents or attachments, may contain information that is confidential or that is privileged. If you are not the intended recipient of this message, please note that the dissemination, distribution, use or copying of this message or any of the accompanying documents or attachments is strictly prohibited. If you believe that you may have received this message in error, please contact me at (302) 658-9200 or by return e-mail.

EXHIBIT J

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December 31, 2007

Sherry L. Rollo, Esquire
WELSH & KATZ, LTD.
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VIA ELECTRONIC MAIL

Re: *sanofi-aventis et al v. Apotex Inc. et al*,
C.A. No. 07-792-GMS

Dear Sherry:

On December 11, 2007, you agreed that the Apotex defendants would not contest jurisdiction in the District of Delaware. Despite your agreement, in the answer filed in Florida, Apotex now denies that the Delaware court has personal jurisdiction over Apotex Inc. Please let me know the basis on which Apotex has denied that there is personal jurisdiction over Apotex Inc. in Delaware after you agreed that defendants would not challenge jurisdiction in Delaware.

Sincerely,


Maryellen Noreika

cc: Richard L. Horwitz, Esquire
Gerald J. Flattmann, Esquire

EXHIBIT K

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January 7, 2008

**Via Electronic Mail (wvuk@kirland.com) &
Confirmation by U.S. Mail**

William T. Vuk, Esq.
Kirkland & Ellis LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022-4611

Re: Sanofi-Aventis et al. v. Apotex Inc. et al.
Civil Action No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.)

Dear William:

We acknowledge receipt of your January 4, 2008 correspondence. We do not agree to transfer the above-captioned case to Delaware. Nor do we agree to a stay of the Florida action pending resolution of any motions to transfer. Sanofi is obligated under the Hatch-Waxman Act to "reasonably cooperate in expediting the action." *E.g.*, 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, we believe that Sanofi should dismiss its Delaware lawsuit against our clients in favor of the Florida action, which necessarily will proceed more quickly to resolution. Please let us know whether your client will agree to dismissal of the Delaware complaint.

I am available this afternoon (after 2pm (CST)) to discuss this and other issues related to the Court's scheduling order.

Very truly yours,

WELSH & KATZ, Ltd.

By: 
Steven E. Feldman

SEF/mh

cc: Alfred J. Saikali, Esq. (asikali@shb.com)
Stephen J. Bronis, Esq. (sbronis@zuckerman.com)
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January 7, 2008

By Electronic Mail

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sefeldman@welshkatz.com

Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,
C.A. No. 07-792 (GMS)
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Steven:

I write to memorialize our meet and confer discussion from earlier today related to the above matters.

In light of sanofi-aventis's first-filed Delaware action, sanofi-aventis requested that the parties meet and confer on the disposition of the second-filed Florida action in an attempt to avoid any unnecessary motion practice before the Court. Specifically, we asked that Apotex agree to the dismissal of the Florida action, transfer to Delaware, or stay pending the disposition of any venue issues in Delaware. Because Apotex has refused to agree that the identical claims and counterclaims of the Delaware and Florida actions should proceed in Delaware along with sanofi-aventis's claims against 13 other defendants, we are left with no choice but to seek relief from the Court.

The following summary confirms the results of the parties' meet and confer today. Please let me know if there is anything you disagree with.

Dismissal or Stay of Claims/Counterclaims Pending In Florida: You confirmed that Apotex would not consent to the dismissal of all claims and counterclaims pending in Florida. You also confirmed that Apotex would not stay any aspect of the second-filed Florida action pending the resolution of any motions that either party might bring.

sanofi-aventis's Dismissal of Their Claims Pending In Delaware: I informed you that sanofi-aventis would not consent to your request to dismiss the claims pending against Apotex in Delaware.

KIRKLAND & ELLIS LLP

Steven E. Feldman, Esq.
January 7, 2008
Page 2

Apotex's Motion to Transfer You confirmed that Apotex intends to file a motion to transfer the first-filed Delaware action to the Southern District of Florida because the Southern District of Florida is a more convenient forum. You explained that Florida is a more convenient venue because Apotex Corp. is headquartered in Florida and, while you could not identify any, you are certain there are potential witnesses/deponents who reside in Florida. You also explained that at this time you were unaware as to whether any Research and Development related to Apotex's generic alfuzosin hydrochloride tablets occurred in Florida. Additionally, you stated that Apotex believes that the second-filed Florida action will be adjudicated faster than the first-filed action in Delaware because Apotex would be on its own against sanofi-aventis as opposed to in one coordinated action in Delaware involving 13 other defendants. You further stated that the Florida Courts issuance of a scheduling order, which I noted was pro forma, setting trial for May 2008 supports the conclusion that the action in Florida would proceed faster than the first-filed Delaware action. At this time, you do not know when Apotex will bring this motion. You also noted that Apotex would not agree to stay the Florida action pending resolution of Apotex's Motion to Transfer. I confirmed that sanofi-aventis would oppose Apotex's motion.

sanofi-aventis's Motion to Transfer and Stay: You confirmed that Apotex would oppose any motion to transfer the second-filed Florida action to Delaware that sanofi-aventis might bring.

The '940 Patent: I notified you that sanofi-aventis does not believe the '940 patent is in dispute against Apotex. You stated that based upon the recent *Forest Labs.* decision you disagreed. However, I informed you that I was unaware of any such decision and you identified no such decision.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. T. Vuk', with a stylized flourish at the end.

William T. Vuk

cc (via email):
Jack Blumenfeld, Esq.
Stephen J. Bronis, Esq.
Richard L. Horwitz, Esq.
Edward A. Moss, Esq.
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EXHIBIT M



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02/28/2008 07:20 PM

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cc William T Vuk <wvuk@kirkland.com>, Alexis Gorton <agorton@kirkland.com>, "Blumenfeld, Jack"



<JBlumenfeld@MNAT.com>, "ASAIKALI@shb.com"
<ASAIKALI@shb.com>

Subject RE: Alfuzosin Litigation, Delaware, Meet and Confer
Proposed Dates

Dear Counsel,

Sanofi-aventis is available for a meet and confer at the time proposed (March 6, 2008 at 2:00 pm EST). So that we have time to review your proposed revisions and so that the parties can have a productive call, could you please circulate your proposed revisions by noon on March 5th?

I will circulate call-in information for the teleconference early next week.

Sincerely,

James

James W. Parrett, Jr.  (302) 351-9678  jparrett@mnat.com

Morris, Nichols, Arsht & Tunnell LLP | 1201 North Market Street | Wilmington, DE 19801

i g v X X r

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE)	
PATENT LITIGATION)	
)	
)	MDL No. 1941
)	

**APOTEX INC.'S AND APOTEX CORP'S RESPONSE AND OPPOSITION
TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTION
PURSUANT TO 28 U.S.C. § 1407**

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I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Apotex, Inc. and Apotex Corp. (collectively “Apotex”) oppose Sanofi-aventis’ and Sanofi-aventis U.S. LLC’s (collectively “Sanofi”) motion pursuant to 28 U.S.C. § 1407 to transfer Case No. 07C61800-FAM presently pending in the Southern District of Florida (the “Florida action”) to the District of Delaware and consolidate it for discovery purposes with several other cases that are pending there (the “Delaware cases”). The Florida action has a discovery cutoff date of August, 2008 and is scheduled for trial in October, 2008; it is scheduled to be completed in seven short months, and certainly well before anything of substance happens in Delaware. The Florida action is well ahead of the Delaware cases, with Apotex and Sanofi already having had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, and served discovery. By contrast, in Delaware discovery has not yet begun. There have been no Rule 26(f) conferences or Rule 16 scheduling orders. Transferring the Florida action to Delaware or consolidating it with the other Delaware cases will needlessly delay rather than promote, the just and efficient conduct of litigation, and is contrary to the public interest.

Unlike other patent litigations, infringement suits brought under the Hatch-Waxman Act require swift and expedited adjudication. *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (noting Congress enacted the Hatch-Waxman Act to “get generic drugs into the hands of patients at reasonable prices – fast”). One of the primary purposes of the Hatch-Waxman Act is to expedite resolution of patent disputes involving drug products in order to facilitate the public’s access to less expensive generic drugs. 21 U.S.C. § 355(j)(5)(B)(iii) (parties required to “reasonably cooperate in expediting the action.”); H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt. 1 at 28, *reprinted in* 1984 U.S.C.C.A.C. 2647. Under the Hatch-Waxman Act, Sanofi’s filing of these infringement suits automatically delays the FDA approval of the generic applications in question for 30 months, unless there is a decision from the district court declaring the patents at

issue invalid or not infringed. A branded pharmaceutical manufacturer, such as Sanofi, therefore has an incentive to delay a final decision for as long as possible. As long as these litigations are pending and do not reach a final verdict Sanofi is assured that generic competition will remain off the market. On the other hand, if a generic drug manufacturer such as Apotex can invalidate or establish non-infringement of an asserted patent before that 30-month period has run, it can get to market earlier, benefitting the public with a less expensive generic equivalent. Thus, Sanofi's motion to consolidate has very little to do with a desire to promote a just and efficient resolution of the actions, and everything to do with slowing down the Florida litigation to ensure that these cases are not decided within the 30 month automatic stay period.

Instead of allowing Sanofi to upset the system, the Florida action should be allowed to move forward at the schedule presently adopted by Chief Judge Moreno. Sanofi already made multiple motions before Judge Moreno in the Florida action to try to stay or delay that case. Each of those motions has been denied, with the Florida Court adhering to its October trial schedule. (Dkt.¹ 23, 36, 48).

Allowing the Florida action to proceed independently also will benefit the Delaware actions. As Sanofi points out one of the primary issues in this case is whether its U.S. Patent No. 4,661,491 ('491 patent) is invalid for obviousness. Obviousness is a question of law based on underlying factual determinations. *Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). If Apotex is successful in invalidating the '491 patent, this decision will be binding on Sanofi and the '491 patent will be invalid as to the Delaware defendants without them having to do anything. *Blonder-Tongue v. University of Illinois Foundation*, 402 U.S. 313 (1971) (holding that a patentee whose patent is held invalid in its suit against one alleged

¹ All references to "Dkt." refer to the docket for Civil Action No. 07-61800 in the Southern District of Florida.

infringer is collaterally estopped from asserting the validity of the patent in a suit against a different alleged infringer).

With respect to 6,149,940 (the '940 patent), Apotex has filed a declaratory judgment action asserting that Apotex's proposed ANDA product does not infringe that patent.² Sanofi admits that Apotex's proposed ANDA product does not infringe the '940 patent. (*see* Dkt. 5 at pg. 6). Therefore, there are no overlapping issues to be decided with respect to Apotex's position on the '940 patent and the several Delaware cases where Sanofi has asserted that other generic defendants' proposed ANDA products do infringe the '940 patent.

Sanofi also mentions claim construction of the '491 patent as a potentially overlapping issue between this case and the Delaware cases. However, claim construction also is a question of law, not a question of fact. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970–71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). to the extent any such issues remain after the Florida case is decided, the Delaware cases will benefit from the work already done on those issues by the Florida Court. And these other rulings in Florida, if not binding, will surely be instructive and also will help to narrow or resolve the issues remaining here to everyone's benefit.

Sanofi also expresses concerns about inconsistent rulings between the Florida and Delaware courts. However, because Florida is scheduled to be completed so far ahead of Delaware, there is little danger of inconsistent rulings. Again, Florida is scheduled to be done before anything substantive has been scheduled to happen in Delaware.

² Although Apotex's ANDA product does not infringe Sanofi's '940 patent, because Sanofi listed the '940 patent in the Orange Book it remains a cloud over Apotex's ANDA product, and is delaying Apotex's ability to get to market. *See Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006). Accordingly, Apotex has counterclaimed against Sanofi seeking patent certainty and a judicial declaration that the '940 patent also is not infringed by its ANDA product. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007).

In the alternative, should the panel determine that these cases should be consolidated for pretrial purposes, that consolidation should take place in the Southern District of Florida before Chief Judge Moreno, who presently is presiding over the Florida action. Such a consolidation and transfer to Florida will enable Judge Moreno to effectively and efficiently administer the cases. Because the Florida action is so far ahead of Delaware, such a consolidation will benefit all parties and the public interest by resulting in a more expeditious resolution of this action than would a transfer and consolidation in Delaware.

II. BACKGROUND

Sanofi brought two identical lawsuits under the Hatch-Waxman Act alleging Apotex infringes one of their patents under 35 U.S.C. § 271(e)(2) by submitting an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”). The first lawsuit was filed in the District of Delaware (“the Delaware action”) and the second was filed days later in the Southern District of Florida (“the Florida action”).

A. Statutory and Regulatory Background

The Hatch-Waxman Act was enacted to promote and expedite the public’s access to lower priced generic drugs. *See* H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt. 1 at p. 28, *reprinted in* 1984 U.S.C.C.A.C. 2647.

To obtain FDA approval to sell a drug that has not been previously approved a company generally must file a new drug application (“NDA”). 21 U.S.C § 355(b). The Hatch-Waxman Act requires NDA holders, such as Sanofi, to submit a list of all patents that cover their approved drugs. 21 U.S.C. § 355(b)(1). These patents are published in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” also known as “the Orange Book.”

Generic companies wishing to market a drug covered by an NDA are permitted to file an ANDA, which substitutes bioequivalence data for the safety and efficacy studies in an NDA. In

cases where the generic manufacturer seeks approval to market the generic pharmaceuticals before the expiration of the patents, the generic must submit a “paragraph IV” certification to the FDA that the applicable patents listed in the Orange Book are invalid or will not be infringed by the manufacture, use, or sale of the drug covered by the ANDA. 21 C.F.R. § 314.94(a)(12)(i)(A). Additionally, the generic must notify the brand manufacturer in writing, per a Paragraph IV letter, that such certification was made. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. 314.95(c)(6).

The submission of a paragraph IV ANDA constitutes a “highly artificial” act of infringement, establishing subject matter jurisdiction for the Court to determine whether the patents identified in the Paragraph IV letter are valid and would be infringed by the sale and manufacture of the proposed generic drug product identified in the ANDA, even though the generic drug product itself has not yet been sold. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). After receiving a Paragraph IV letter, brand manufacturers are given 45 days to bring a suit for patent infringement under 35 U.S.C. § 271(e)(2); 21 U.S.C. § 355(j)(5)(B)(iii). The mere act of filing within 45 days prevents the FDA from approving the generic’s ANDA for thirty (30) months unless the generic prevails on the merits at the District Court level before that time. 21 U.S.C. § 355(j)(5)(B)(iii). Until a final decision is reached, the brand manufacturer enjoys unchallenged exclusivity in the marketplace. In exchange for this automatic 30-month stay, Congress also imposed the express statutory requirements that all parties “reasonably cooperate in expediting the action.” 21 U.S.C. § 355(j)(5)(B)(iii); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 403 F.Supp.2d 484, 490 (E.D. Va. 2005) (“Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires

that, in these actions, ‘each of the parties shall reasonably cooperate in expediting the action.’” (quoting analogous provision of 21 U.S.C. § 355(c)(3)(C))), *rev’d on other grounds*, 499 F.3d 1299 (Fed. Cir. 2007) (reversing the grant of summary judgment of infringement on the merits).

Under these statutory regulations, the generic is entitled to expeditious judicial resolution of this matter to get its less expensive generic equivalents to market. Any delay in resolution significantly favors the brand pharmaceutical company, which gets to maintain its monopoly profits and higher prices until the patent dispute is resolved.

B. Statement of Facts

Apotex, Inc. submitted its ANDA No. 79-013 seeking FDA approval to market and sell a generic version of Sanofi’s Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product before the patents that Sanofi has listed with the FDA as covering that product expire. (Dkt. 3 at Answer ¶ 12). The ANDA was prepared in Canada, where Apotex, Inc. is located. (Dkt. 3 at Answer ¶ 3). Apotex, Inc. provided Sanofi with Paragraph IV notice of its ANDA No. 79-013, certifying that Sanofi’s U.S. Patent Nos. 4,661,491 and 6,149,940 (“the ’491 patent” and “the ’940 patent” respectively) were not infringed or invalid. (Dkt. 3 at Counterclaim Paragraphs ¶¶15, 16). Sanofi filed suit, within 45 days of receiving Apotex’s notice letter, two identical lawsuits naming Apotex, Inc. and Apotex Corp. as parties. The first lawsuit filed on December 6, 2007 in the District of Delaware and the second, days later, on December 10, 2007, in the Southern District of Florida. On December 28, 2007, the Apotex parties answered, counterclaimed and consented to proceed in the Southern District of Florida. The Apotex parties have answered and counterclaimed in the Delaware action, but preserved its position that this matter should be transferred to the Southern District of Florida and joined with the co-pending litigation.

The Florida action has progressed at a fast-pace. The parties already have had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, Apotex has served document production requests and interrogatories, and the parties are negotiating a protective order to govern discovery. The Florida Court has set a discovery cutoff for August, 2008 and a trial in October, 2008. The Delaware action, however, has not progressed passed initial pleadings.

III. ARGUMENT

The overwhelming public interest is best served in this matter by allowing the Florida action to remain separate and continue to progress on the expedited trial track ordered by the Judge. Sanofi's argument that consolidation will promote the just and efficient conduct of these actions is nonsense. Sanofi has no interest in promoting an efficient result. Rather, Sanofi is using this motion for consolidation to derail the fast track the Florida action is on. In reality there are no advantages to a transfer and consolidation of the Florida action. The case is progressing at an exponentially faster pace than the other Delaware actions. Requiring the Florida action to be consolidated would only slow this litigation and be contrary to the public's interest in readily available generic drugs.

A. Apotex Will Suffer Actual Prejudice Through the Transfer and Consolidation of This Action

Apotex will be prejudiced by a transfer and consolidation of the Florida action. The Florida Court already entered a scheduling order and set a discovery cutoff date of August, 2008 and a trial date for October, 2008. (Dkt. 23). The consolidation and transfer of this action will no doubt impact this trial date and thus Apotex's ability to get its generic alfuzosin product to market sooner. Discovery in the Florida action is already well underway – with initial disclosures, document production and interrogatory requests already having been served. With

the August discovery cutoff date only five months away, discovery will be substantially underway if not completed by the time the Panel rules on Sanofi's motion and as such consolidation of the Florida action is improper. *See e.g. In re Celotex Corp. "Technifoam" Products Liability Litigation*, 68 F.R.D. 502 (J.P.M.L. 1975) (consolidating only nine out of ten cases when the tenth case apparently completed discovery.); *In re Women's Clothing Antitrust Litigation*, 455 F. Supp. 1388 (J.P.M.L. 1978) (denying to consolidate cases where substantial discovery has taken place). Any argument that discovery in the Florida action will not go forward is illusory. The Florida court has already denied Sanofi's emergency motion to stay the action pending the outcome of Sanofi's motion to consolidate. (Dkt. 48). Discovery is progressing and will be completed in August, 2008. (Dkt. 51 at 4, granting Apotex's motion for entry of protective order to govern discovery and noting that "Sanofi was scheduled to begin producing documents on February 18, 2008, and the discovery deadlines and trial date are fast approaching.")

Amazingly, Sanofi contends that Apotex will need so much discovery that the Florida action must be consolidated, specifically stating Apotex will "require at least 100 fact depositions." *See Sanofi's Brief in Support of Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. § 1407* at 16. When a plaintiff starts making arguments for its adversaries it is usually a good time to pause, reflect and question the merits of those arguments. Apotex is prepared to conduct the necessary discovery in the amount of time allotted by the Florida Court. The Florida Court, after considering Sanofi's arguments twice, is prepared to move forward with the litigation on the scheduled track. The only reason the Florida action isn't further along in discovery is because Sanofi was exhausting every option available to delay the process.

Apotex has made every effort to proceed expeditiously in accordance with the requirements of the Hatch-Waxman Act and Florida Court's scheduling orders. This motion for consolidation is the next in Sanofi's many attempts to slow down this litigation, and thus preserve its monopoly on the alfuzosin market, with corresponding prejudice to Apotex's ability to get generic alfuzosin to market.

B. Sanofi's Arguments Ignore that Allowing the Florida Action to Proceed Independently Promotes the Public Interests and the Purpose of the Hatch-Waxman Act

The public interest and The Hatch-Waxman Act require the parties to expedite these actions. Sanofi's argument that consolidation will serve the purpose of the Hatch-Waxman Act ignores the requirement to proceed to a speedy resolution. The Hatch-Waxman Act was enacted to promote the overwhelming public interest of readily available generic drugs. *See* H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt 1 at p. 28, *reprinted in* 1984 U.S.C.C.A.C. 2647. The public benefits from a just and speedy adjudication of the brand-name maker's patent claims. A transfer of the Florida action to a transferee MDL Court and then subsequent remand to the original transferor court will only disrupt and delay reaching a final judgment.

Sanofi's motion for consolidation is not motivated by promoting the public interests or serving the purpose of the Hatch-Waxman Act. Sanofi seeks to take full advantage of the statutory 30-month stay allowed under the Hatch-Waxman Act. A Hatch-Waxman infringement suit delays the FDA's approval of the generic application for 30 months unless a "final decision" declaring the patent invalid or not infringed occurs first. 21 U.S.C. § 355(j)(B)(iii). During this stay, an ANDA applicant, such as Apotex, cannot market its product and the brand-name maker, such as Sanofi, enjoys unchallenged exclusivity in the marketplace. Sanofi can ensure the largest possible period of exclusivity simply by avoiding going to trial for the duration of the 30 month stay at the FDA. Accordingly, unlike a typical patent plaintiff, Sanofi's interest does not lie with

expediting these litigations. Sanofi's transfer motion is calculated to delay generic competition for Sanofi's Uroxatral[®] products as long as possible.

Transferring and consolidating these cases will only delay the proceedings and work contrary to the well-established public interest and the purpose of the Hatch Waxman Act. The Florida action is moving towards an October, 2008 trial date. Substantial pre-trial activity has already taken place including the Fed. R. Civ. P. 26(f) conference, exchange of Fed. R. Civ. P. 26(a)(1) disclosures, and service of document production requests and interrogatories. Despite Sanofi's attempts to slow the Florida action, the Florida Court has continuously upheld the fast-paced schedule.

Granting Sanofi's motion would require the Florida action to be transferred from its original court to an MDL court. Such a transfer will only disrupt the progress already made in the Florida action. *In re Gasoline Lessee Dealers*, 479 F.Supp. 578, 581 (J.P.M.L. 1979) ("Inclusion of the actions now before us in coordinated or consolidated proceedings would, we are convinced, disrupt the orderly progress that is presently being made in the actions in each respective district and would result in no significant benefits to the parties, the witnesses or the judiciary."). The delay and disruption caused by the transfer of the cases would no doubt delay the October, 2008 trial date already set in the Florida action and frustrate the public interest of providing for readily available generic drugs.

Allowing both parties to remain on the calendar of their respective trial courts will assist in the expeditious resolution of the cases. Granting a transfer and consolidation would be a disservice to the parties and contrary to the public interest of a speedy and efficient resolution of these cases.

C. Transfer and Consolidation Will Not Further the Just and Efficient Conduct of the Actions

The just and efficient conduct of these actions will not be promoted by consolidation. Sanofi does not meet its burden of showing that transfer and consolidation will expedite the proceedings. The more likely result of any transfer and consolidation will be to delay the resolution of the pending Florida action and complicate pretrial proceedings.

i. The Pending Actions Do Not Share Sufficient Common Questions

Sanofi cannot succeed in consolidating the pending cases because the cases may involve some common questions of fact. *In re Eli Lilly and Co.*, 446 F. Supp. 242, 243-44 (J.P.M.L. 1978) (holding that the movant has the burden of demonstrating that common factual questions are sufficiently complex or that the accompanying discovery is so time consuming as to justify transfer); *In re Cessna Aircraft Distributorship Antitrust Litig.*, 460 F.Supp. 159, 161-62 (J.P.M.L. 1978) (noting that when common facts and questions exist “a mere showing that such questions exist is not sufficient, in and of itself, to warrant transfer”). Sanofi, as the movant, must show that there are common questions of fact and law that are complex, unresolved and numerous enough to justify transfer. *In re Royal American Indust. Securities Litig.*, 407 F. Supp. 242, 243 (J.P.M.L. 1976); *In re Scotch Whiskey Antitrust Litig.*, 299 F. Supp. 543, 544 (J.P.M.L. 1969); *In re Garrison Diversion Unit Litig.*, 458 F.Supp. 223, 225 (J.P.M.L. 1978).

Among the pending cases, there are likely substantial differences in Apotex’s and the other Defendants’ proposed ANDA formulations. The other Defendants have been sued for the infringement of not only the ’491 patent but also the ’940 patent. Sanofi has not sued Apotex for infringement for the ’940 patent but Apotex has counterclaimed seeking a declaration that its ANDA product does not infringe the patent because Apotex’s proposed drug product is **different**

from what is claimed in the '940 patent. In fact, it is likely that Apotex's ANDA product is substantially different (and therefore not infringing) from the other Defendants.

Although, Sanofi offers citations to cases involving Hatch-Waxman litigation, the cases are factually opposite to the instant situation, and therefore offer no support for their assertion. For instance, *In re Desloratadine Patent Litig.*, 502 F.Supp.2d 1354 (J.P.M.L. 2007) was cited for Sanofi for the proposition that ANDA litigations often share common questions of law and fact allowing for consolidation. However, in *Desloratadine*, none of the separate actions had progressed to the point Apotex and Sanofi have in Florida. None of the *Desloratadine* actions were already involved in discovery much less had a scheduling order and a set trial date approaching in seven short months. Additionally, Sanofi cites *In re Rivastigmine Patent Litig.*, 360 F.Supp.2d 1361 (J.P.M.L. 2005) to emphasize the Panel's consolidation of actions involving branded pharmaceutical products. Sanofi, however, fails to mention that all parties in *Rivastigmine* consented to the consolidation. *Id.*

None of these cases are factually identical to the instant situation where one of the pending actions has progressed substantially. Here, the parties have exchanged initial disclosures, Apotex has served both interrogatories and production requests, a protective order is being negotiated pursuant to a Court Order (Dkt. 51), and a trial date is approaching in seven months. Any common questions of fact or law that may exist cannot outweigh the benefits of allowing the Florida action to proceed to resolution on its expedited track.

ii. Transfer and Consolidation Does Not Favor Convenience of the Parties and Witnesses

Sanofi asserts that transfer and consolidation would serve the convenience of the parties and witnesses. The Florida litigation has no connection to Delaware, where Sanofi seeks to have the cases consolidated. Apotex Corp.'s headquarters is located in Florida and Apotex, Inc. is

located in Canada. Sanofi-Aventis U.S. is located in New Jersey and its parent, Sanofi-Aventis is located in France. Apotex does not have documents, offices or witnesses located in Delaware.

The convenience of the witnesses also weighs against consolidation. All persons knowledgeable about the contents of Apotex's ANDA, and therefore potential witnesses, are located in Florida or Canada. Sanofi has alleged that Apotex Corp. is "jointly and severally liable" for Apotex, Inc.'s alleged infringement of the '491 patent, and has further accused Apotex Corp. of participating in, aiding and abetting, inducing and contributing to "Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA." (Dkt.1 at ¶ 15). While Apotex denies these allegations (or even that they state a claim for infringement), the situs of these alleged acts, and any related Apotex Corp. documents and witnesses, necessarily would be Florida, where Apotex Corp. is located.

Accordingly, at least the Apotex Corp. witnesses will be inconvenienced by a transfer, and Delaware is no more convenient than Florida for any of the other witnesses.

D. Alternatively, If The Panel Consolidates Coordinated Pretrial Proceedings Should Proceed in The Southern District of Florida

Apotex believes that consolidating the Florida action is inappropriate. However, if the Panel decides to consolidate the Florida action with the other pending actions, it would further promote the just and efficient conduct of the litigation to coordinate the pretrial activities in the Southern District of Florida. It is already evident, based on the expedited pace of the Florida action, that the Florida Court will be able to dispose of these cases faster than the District of Delaware. Therefore, if the Florida action is consolidated, transfer and consolidation in the Southern District of Florida promises to better improve judicial economy and bring the swiftest resolution to the pending actions.

IV. CONCLUSION

For the foregoing reasons *Plaintiffs' Motion for Transfer and Consolidate for Pretrial Proceedings* should be denied.

V. RESPONSE TO PLAINTIFFS' MOTION TO TRANSFER AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS

In response to Sanofi's numbered averments, Apotex responds:

1. Apotex Inc. and Apotex Corp. admit only that *Sanofi-aventis et al v. Apotex Inc. et al.*, No. 07-792 ("Apotex Delaware action") and *Sanofi-aventis et al v. Apotex Inc. et al.*, No. 07-61800 ("Apotex Florida action") involve the infringement, validity and enforceability of the '491 patent titled "Alfuzosine Compositions and Use." Apotex Inc. and Apotex Corp. have counterclaimed for a declaratory judgment of non-infringement of the '940 patent in the Apotex Delaware action and the Apotex Florida action. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 1 and on that basis denies the same.

2. Apotex Inc. and Apotex Corp. admit that the '491 and '940 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the applicant for NDA No. 21-287.

3. Apotex Inc. and Apotex Corp. admit only that Apotex Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10 mg strength. Apotex Inc. and Apotex Corp. admit Apotex Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 and on that basis denies the same.

4. Apotex Inc. and Apotex Corp. admit that Apotex Inc. provided Sanofi with notice of its ANDA No. 79-013; that such notice satisfied all statutory and regulatory requirements, and that Plaintiffs received notice on or about October 25, 2007. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 4 and on that basis denies the same.

5. Apotex Inc. and Apotex Corp. admit that on or about August 14, 2007, Apotex Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent. Apotex Inc. and Apotex Corp. admit that on or about October 25, 2007, Apotex Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

6. Denied.

7. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the averments in Paragraph 7 and on that basis denies the same.

8. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the averments in Paragraph 8 and on that basis denies the same.

9. Apotex Inc. and Apotex Corp. admit that on December 6, 2007, Sanofi filed a complaint against Apotex Inc. and Apotex Corp. for the infringement of the '491 patent. Apotex Inc. and Apotex Corp. admit this lawsuit resulted in Civil Action No. 07-792. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 9 and on that basis denies the same.

10. Apotex Inc. and Apotex Corp. admit only that Apotex Inc. and Apotex Corp. have filed their answer and counterclaim and Sanofi has filed its reply in Civil Action No. 07-792. Apotex Inc. and Apotex Corp. admit to filing a motion to transfer or stay on January 24, 2008. Apotex, Inc. and Apotex Corp. admit Sanofi filed its opposition brief on January 31, 2008. Apotex Inc. and Apotex Corp. deny that a reply has not been filed. Apotex Inc. and Apotex Corp. admit they did not dispute jurisdiction or venue for purposes of this action. However, Apotex Inc. and Apotex Corp. denied that Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent infringement or that Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Apotex Inc. or Apotex Corp. Further, Apotex Inc. and Apotex Corp did not deny that the District of Delaware was a possible venue but did state that the Southern District of Florida is a more convenient venue and that the Delaware action should be transferred there and joined with the copending civil action no. 07 C 61800 (S.D. Fla.). Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 10 and on that basis denies the same.

11. Apotex Inc. and Apotex Corp. admit Sanofi initiated suit against Apotex Inc. and Apotex Corp. within the statutory 45-day window. Apotex Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 11 and on that basis denies the same.

12. Apotex Inc. and Apotex Corp. are without sufficient knowledge to admit or deny the averments, which are therefore denied.

13. Apotex Inc. and Apotex Corp. admit Sanofi filed an identical lawsuit against Apotex Inc. and Apotex Corp. on December 10, 2007 in the Southern District of Florida. Apotex

Inc. and Apotex Corp. lack sufficient knowledge to form a belief as to the truth or falsity of the remaining averments in Paragraph 13 and on that basis denies the same.

14. Denied. If Sanofi really were concerned about jurisdiction in Delaware, it could have sued Apotex here anytime during the first 24 days of that 45 day period, and still had sufficient time to file suit in Florida after Apotex, Inc. answered, if Apotex, Inc. had challenged personal jurisdiction.

15. Apotex Inc. and Apotex Corp. admit Sanofi filed an identical lawsuit against Apotex Inc. and Apotex Corp. on December 10, 2007 in the Southern District of Florida. Apotex denies the Florida action is at an early stage. Litigation in the Florida action is well underway. The Florida Court already set a discovery schedule with a discovery cut-off of August 6, 2008 and a trial date of October 6, 2008. Apotex and Sanofi already have had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, and Apotex has served document production requests and interrogatories.

16. Apotex Inc. and Apotex Corp. admit to answering the Delaware Complaint on January 2, 2008 and that Apotex Inc. and Apotex Corp. did not dispute jurisdiction or venue for purposes of this action. Apotex Inc. and Apotex Corp. admit that Sanofi replied to Apotex Inc.'s and Apotex Corp.'s counterclaims on January 3, 2008.

17. Apotex Inc. and Apotex Corp. admit Sanofi moved to transfer the Florida action to Delaware on January 8, 2008 and that Apotex Inc. and Apotex Corp. filed its opposition brief on January 28, 2008. Apotex Inc. and Apotex Corp. deny that a reply brief has not been served. The Apotex parties served the reply brief on February 11, 2008.

18. Apotex Inc. and Apotex Corp. disagree with Sanofi's conjecture in paragraph 18. To the extent that there is an averment of fact in this paragraph, Apotex Inc. and Apotex Corp.

are without sufficient knowledge to admit or deny the averment, which is therefore denied. Sanofi has not sued Apotex for infringement for the '940 patent but Apotex has counterclaimed seeking a declaration that its ANDA product does not infringe the patent because Apotex's proposed drug product is **different** from what is claimed in the '940 patent. In fact, it is likely that Apotex's ANDA product is substantially different (and therefore not infringing) from the other Defendants.

19. Apotex Inc. and Apotex Corp. disagree with Sanofi's conjecture in paragraph 19. To the extent that there is an averment of fact in this paragraph, Apotex Inc. and Apotex Corp. deny the averment. Delaware has no connection to the Florida action. Apotex Corp. is located in Florida and therefore, Florida is the more convenient location.

20. Apotex Inc. and Apotex Corp. disagree with Sanofi's conjecture in paragraph 20. To the extent that there is an averment of fact in this paragraph, Apotex Inc. and Apotex Corp. deny the averment. Transfer of the Florida action to Delaware will only unnecessarily delay a litigation set for trial in seven months. This will not promote a just and efficient resolution much less serve the interests of judicial economy.

21. Apotex Inc. and Apotex Corp. disagree with Sanofi's conjecture in paragraph 21. To the extent that there is an averment of fact in this paragraph, Apotex Inc. and Apotex Corp. are without sufficient knowledge to admit or deny the averment, which is therefore denied. Apotex Inc. and Apotex Corp. request that the Panel deny Sanofi's motion and allow the Florida action to continue and go to trial in October 2008 as scheduled.

GENERAL DENIAL

Any allegation in Plaintiffs' Motion to Transfer and Consolidate for Pretrial Proceedings not expressly admitted by Apotex Inc. and Apotex Corp. are hereby denied.

Dated: February 25, 2008

A handwritten signature in black ink, appearing to read "Steven E. Feldman", written over a horizontal line.

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Counsel for Defendants Apotex, Inc. and
Apotex Corp.

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE ALFUZOSIN HYDROCHLORIDE)	
PATENT LITIGATION)	
)	
)	MDL No. 1941
)	

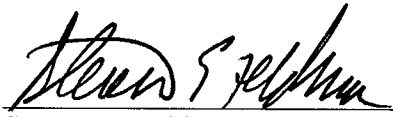
PROOF OF SERVICE

I certify that on February 25, 2008, a true and correct copy of the following:

1. Apotex Inc.'s and Apotex Corp.'s Response and Opposition to Plaintiffs' Motion for Transfer of Action Pursuant to 28 U.S.C. §1407; and
2. Proof of Service

was served via federal express on the interested parties as listed in the attached Panel Attorney Service List.

February 25, 2008


Steven E. Feldman

**Judicial Panel on Multidistrict Litigation - Panel Attorney Service List
for
MDL 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation**

***** Report Key and Title Page *****

Please Note: This report is in alphabetical order by the last name of the attorney. A party may not be represented by more than one attorney. See Panel rule 5.2(c).

Party Representation Key

- * Signifies that an appearance was made on behalf of the party by the representing attorney.
 - # Specified party was dismissed in some, but not all, of the actions in which it was named as a party.
- All counsel and parties no longer active in this litigation have been suppressed.

This Report is Based on the Following Data Filters

Docket: 1941 - Alfuzosin Hydrochloride PAT

For Open Cases

Docket: 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation

Status: Pending on / /

Transferee District: Judge:

Printed on 02/15/2008

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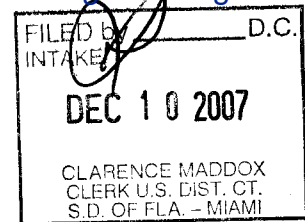
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 07-61800

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

CIV-MORENO

vs.

MAGISTRATE JUDGE
SIMONTON

APOTEX INC. and
APOTEX CORP.,

Defendants. /

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Apotex Inc. and Apotex Corp., hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned

subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff sanofi-aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral[®] brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral[®] in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral[®].

Acts Giving Rise to this Action

Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a

proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j)(2)(A)(vii)(IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That Defendants have infringed the '491 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex Inc.'s ANDA identified in this Complaint shall not be earlier than the expiration date of the '491 patent, including any extensions;
- C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently

enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated this 10th day of December, 2007.
Miami, Florida

Respectfully submitted,



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Attorney for Plaintiffs sanofi-aventis and
sanofi-aventis U.S. LLC

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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION**

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,
Defendants.

**PLAINTIFFS' MOTION TO TRANSFER OR STAY
AND SUPPORTING MEMORANDUM OF LAW**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully move the Court to transfer this action to the District of Delaware where an identical, parallel, first-filed action is currently pending. Defendants Apotex Corp. and Apotex Inc. do not contest personal jurisdiction in Delaware and admit that venue in that forum is proper. Plaintiffs' choice of forum, the first-filed rule, and the interests of justice and convenience to the parties and witnesses favor transfer of this action to Delaware where it will proceed before the same Judge and Magistrate Judge as two related actions involving 13 other defendants and the parallel action against Apotex Corp. and Apotex Inc. Alternatively, Plaintiffs respectfully move this Court to stay the present action pending the disposition of any transfer issues raised by Defendants in the first-filed forum.

Counsel for Plaintiffs certify that pursuant to Local Rule 7.1.A.3(a) it has met and conferred with counsel for Defendants in an effort to resolve the issues raised by Plaintiffs' Motion to Transfer or Stay. The parties were unable to resolve those issues.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully requests that the Court enter an Order granting Plaintiffs' Motion to Transfer or Stay.

MEMORANDUM OF LAW

This is an action brought under 35 U.S.C. § 101 *et seq.* and the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully submit this memorandum in support of their motion to transfer this action to the District of Delaware where an identical, parallel, first-filed action and two related cases against 13 other defendants are currently pending. Alternatively, Plaintiffs request that the Court stay this action pending the resolution of any venue issues raised in the Delaware action by Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex").

The District of Delaware is Plaintiffs' forum of choice and the first-filed forum. This is true not only for the parallel proceeding against Apotex, but also for sanofi-aventis's claims against 13 other defendants. Plaintiffs would not have even filed this action if Apotex had timely confirmed what it has now admitted in its pleadings and in its representations to Plaintiffs — that it does not contest personal jurisdiction in Delaware and that venue is appropriate in that forum.

But rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to game the system and engage in forum-shopping by arguing that the Southern District of Florida is more convenient and will adjudicate the parties' claims more quickly. There is scant support for either of these assertions as the majority of Apotex's documents and witnesses are likely located in Canada where it develops its generic products, and the issues involved in this patent litigation are sufficiently complex, and potential discovery so far-reaching, that they will likely take a considerable time to adjudicate regardless of the forum

in which they proceed. If Apotex's attempt to make an end-run around sanofi-aventis's choice of forum is successful, the result will be contrary to the interests of justice, leading to a waste of time and resources on duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses which will have to proceed in two separate districts. Apotex's tactics will not only impact the parties in this case, but also the 13 additional defendants in Delaware where sanofi-aventis's other patent infringement actions will proceed regardless of what happens in this jurisdiction. Consequently, the Court should follow the time-honored rule of allowing actions to proceed in the first-filed forum and transfer this case to Delaware so that all claims for patent infringement may proceed in the same court and before the same Judge and Magistrate Judge in a coordinated manner.

Alternatively, if the Court does not transfer at this time, Plaintiffs respectfully request that it stay the present action and defer to the first-filed District of Delaware on the issue of venue while the parties continue to litigate their claims and defenses in that forum.

BACKGROUND

I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in the state of New Jersey.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. Apotex Inc. and Apotex Corp.

sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed \$1 billion (Canadian \$) per year." Ex. 1, The Apotex Group Corporate Info.¹

II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 (issued April 28, 1987) ("the '491 patent"), titled "Alfuzosine Compositions and Use." It is also a current assignee of United States Patent No. 6,149,940 (issued November 21, 2000) ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."² Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287.

III. Infringement Of Sanofi-Aventis's Patents By The ANDA Filers

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation and/or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale

¹ True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of William T. Vuk in Support of Plaintiffs' Motion to Transfer or Stay.

² Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.

of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. 2, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. 3, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

IV. Commencement Of The First-Filed District Of Delaware Actions

A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In the District of Delaware

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try each of sanofi-aventis's claims against all defendants, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in the United States District Court for the District of Delaware against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.³

³ In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940

See Ex. 4, Delaware Complaint No. 07-572; Ex. 5, Delaware Complaint No. 07-574.

B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In The District Of Delaware Shortly Thereafter

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. 6, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent. Ex. 7, Apotex Delaware Complaint. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

C. Apotex Agreed Not To Contest Jurisdiction In The District Of Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,⁴ Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. See Ex. 9, 12/06/07 W. Vuk ltr to B. Sherman. It was only after that period ran that Apotex represented

patent alone against four additional defendants.

⁴ On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. 8, Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al*, No. Civ. 07-204-SLR at 3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. 8, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4.

that it would not contest jurisdiction in Delaware. Ex. 10, 12/11/07 M. Noreika email to S.

Rollo; Ex. 11, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the complaint in Delaware and conceded that jurisdiction and venue were proper in Delaware:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." *See* Ex. 12, Apotex Delaware Answer And Counterclaims ¶ 7.
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it" *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action" *Id.* ¶ 10.

Despite these clear admissions to the Delaware court as to the appropriateness of jurisdiction and venue, Apotex has indicated that it will move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* Ex. 12 ¶ 10; Ex. 13, 01/07/08 S. Feldman ltr to W. Vuk; Ex. 14, 01/07/08 W. Vuk ltr to S. Feldman.

All three first-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and the same Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. *See* Ex. 15, Delaware Docket Sheets.⁵

V. Plaintiffs Brought The Present Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware

Apotex's refusal to consent to jurisdiction in Delaware within the 45-day window to bring

⁵ One additional protective suit is currently pending against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. Plaintiffs have not served the complaint in that action and expect that their claims against the Aurobindo defendants will proceed in the District of Delaware where jurisdiction and venue are proper with respect to both parties.

suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See PDL BioPharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over Apotex, this is the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring this second-filed action within the 45-day window on December 10, 2007.⁶ Ex. 16, Florida

⁶ The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

Complaint. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing so that sanofi-aventis could voluntarily dismiss the Florida complaint.

It is now clear that this tactic was an attempt to make an end rule around Plaintiffs' choice of forum. Apotex filed its Answer and Counterclaims in this action on December 28, 2007, one business day before answering the first-filed Delaware action, in a thinly-veiled attempt to manufacture an argument that this action is at a more advanced state than the first-filed Delaware actions.⁷ See Ex. 17, Florida Answer And Counterclaims; Ex. 18, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that this forum is "more convenient" with the "fact" that this action has progressed farther than the Delaware actions because it filed its answer in Florida one business day before answering in Delaware. As discussed below, similar attempts by ANDA filers to game the system and to secure the forum of their choice at the expense of the plaintiff have failed.

ARGUMENT

I. All Relevant Factors Favor Transfer To Delaware Where Identical Claims And Counterclaims Are Pending With Related Claims Against 13 Other Defendants

Where venue is proper, a federal court, "[f]or the convenience of parties and witnesses, in the interest of justice, may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Thus, the question of whether to transfer is a two-part inquiry. First, the transferee forum must be one in which the action could originally have been

⁷ In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action" Ex. 17 ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest the Delaware court's personal jurisdiction over Apotex Inc. Ex. 12 ¶ 8; *see also* Ex. 10; Ex. 11.

brought. Second, the Court must balance factors such as the plaintiff's choice of forum, the interests of justice, and the convenience of the parties and witnesses in deciding whether on the whole they favor transfer. *Manuel v. Convergys Corp.*, 430 F.3d 1132, 1135 n.1 (11th Cir. 2005).

There is no dispute that this Court has the power to transfer this action to the District of Delaware as, unlike the circumstances of many motions to transfer, sanofi-aventis and Apotex agree that jurisdiction and venue are proper in Delaware. The Court should exercise its power and transfer this action to the first-filed forum for adjudication with the parties' identical claims pending in that court along with two related patent infringement litigations involving the same patents-in-suit and reference drug—actions that will proceed regardless of what happens in this forum. First, Delaware is both Plaintiffs' forum of choice and the first-filed forum, two factors that weigh heavily in favor of transfer. Second, transfer would avoid the duplicative efforts and costs of two separate courts conducting extensive pretrial activities and prevent potentially inconsistent rulings on critical issues such as claim construction and summary judgment. Finally, although Apotex claims that it would be more convenient for it to proceed in this forum, that convenience is minimal as most of its relevant witnesses and documents are likely located in Canada where it develops generic products. Additionally, it is likely that this action will take a significant amount of time to adjudicate regardless of where it proceeds in light of the complex nature of the case and the expected scope of discovery. Any minimal added burden of litigating in Delaware, where Apotex has recently litigated several other ANDA actions without moving to transfer, is heavily outweighed by the interests of judicial economy and certainty of patent rights as well as the inconvenience the parties would experience by litigating the same issues in two separate judicial districts. *See Abbott*, 2006 WL 850916, at *8 (finding an ANDA filer's convenience argument less persuasive when it had litigated multiple ANDA cases in the forum without complaint).

A. Both the Plaintiffs' Choice of Forum and the First-Filed Rule Favor Transfer

Plaintiff's choice of forum weighs in favor of a request to transfer and should not be disturbed unless clearly outweighed by other considerations. *Cf. Robinson v. Giarmarco & Bill, P.C.*, 74 F.3d 253, 260 (11th Cir. 1996) (refusing to transfer outside of plaintiffs' forum where such a transfer would merely shift the burdens on the parties). Here, sanofi-aventis chose the District of Delaware because it was the district where Plaintiffs could bring each of the ANDA filers and related defendants under the jurisdiction of the court so that all claims and counterclaims concerning Uroxatral® and the listed patents could be adjudicated in a single forum. Plaintiffs were only forced to bring this second-filed action because Apotex refused to confirm that it would not contest jurisdiction in Delaware within the 45-day window Plaintiffs had to bring suit under the Hatch-Waxman Act. *See, e.g.*, Ex. 9. As discussed above, the law remains unclear as to whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act, namely the 30-month stay of approval of the proposed generic product, if its action, properly brought within the 45-day window, is later dismissed for lack of personal jurisdiction. *See Abbott*, 2006 WL 850916, at *8; *PDL*, 2007 WL 2261386, at *2. Now that Apotex has acknowledged that it does not contest personal jurisdiction in Delaware, the Court should transfer this action to Plaintiffs' forum of choice. *See* Ex. 10; Ex. 11; Ex. 12 ¶¶ 7-10.

Transfer under this set of facts would also comport with the 11th Circuit's "first-filed" rule. Under that standard, if two actions involving the same parties and identical issues are pending in different districts, the first-filed action should typically be given priority and be allowed to proceed in favor of the later action. *See Manuel*, 430 F.3d at 1135-38 ("[W]here two actions involving overlapping issues and parties are pending in two federal courts, there is a strong presumption across the federal circuits that favors the forum of the first-filed suit under the first-filed rule."); *Philibert v. Ethicon, Inc.*, No. 04-81101-CIV, 2005 WL 525330, at *1 (S.D.

Fla. Jan. 14, 2005). Contrary to Apotex's unsupported assertions, this rule applies even where plaintiff files both actions, a measure that courts have recognized as necessary under the Hatch-Waxman Act. Ex. 14; *PDL*, 2007 WL 2261386, at *2; *see also Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F. Supp. 1200, 1202-03 (S.D. Fla. 1987) (rejecting defendants' assertion that a plaintiff must show a change of circumstances when moving under § 1404 and ordering transfer to the first filed forum where four related litigations involving these and other defendants were already pending).⁸

Sanofi-aventis filed the Delaware action against Apotex on December 6, 2007. The Florida action was filed on December 10, 2007, but never served. Both the Delaware and the Florida actions raise the same issues—namely, whether Apotex's proposed generic version of Uroxatral® infringes any valid and enforceable claim of the '491 patent, and to the extent Apotex's counterclaims are not dismissed, whether that product infringes any valid and enforceable claim of the '940 patent. Consequently, the Court should transfer this action under the first-filed rule. *Philibert*, 2005 WL 525330 at *2 (transferring to the first-filed forum where identical claims were pending to serve the interests of justice); *Tiber Labs., LLC v. Cypress Pharm., Inc.*, No. 2:07-CV-0014-RWS, 2007 WL 3216625, at *2-3 (N.D. Ga. May 11, 2007).

⁸ The first-filed rule is measured by which action was filed first, not by when counterclaims are first filed. Consequently, Delaware is the first-filed forum in this case, even though Apotex's counterclaims with respect to the '940 patent were filed in this District one business day before filing them in Delaware. *See Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F. Supp. 2d 738, 740-41 (E.D. Wis. 2003) (rejecting a similar argument concerning declaratory judgment counterclaims asserted in the second-filed action concerning patents not initially at issue in the first-filed action because "[t]he issue, however, is not which of the claims was filed first, but rather which action was filed first."); *Versus Tech., Inc. v. Hillenbrand Indus., Inc.*, No. 1:04-CV-168, 2004 WL 3457629, at *6-7 (W.D. Mich. Nov. 23, 2004); *cf. Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 831-32 (2002) (holding that counterclaims cannot serve as the basis for "arising under" jurisdiction under the well-pleaded complaint rule).

B. The Interests of Justice Can Only Be Served By Transfer To The Forum Where All Others Claims Concerning The Patents Are Pending

As the Federal Circuit has held, "consideration of the interest of justice, 'may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.'" *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1565 (Fed. Cir. 1997).

For example, in *Alere Medical, Inc. v. Health Hero Network, Inc.*, a first-filed action was brought in Illinois for infringement of plaintiff's patent. No. C- 07-05054 CRB, 2007 WL 4351019, at *1 (N.D. Cal. Dec. 12, 2007). The accused infringer subsequently filed a separate declaratory judgment action in California concerning seven other patents owned by the patentee, but not at issue in the first-filed action. The second-filed court granted the accused infringer's motion to transfer its declaratory judgment action to the first-filed forum because, *inter alia*, the related actions "share[] common technology and products, common parties, and overlapping issues of infringement and validity. Having all the patents before a single judge will obviate the need for duplicative tutorials and evidence, and will facilitate a global settlement." *Id.* Rejecting the patentee's argument that transfer would be inconvenient in light of the location of relevant witnesses, parties, and documents, the court stated that "the pertinent question is not simply whether *this* action would be more conveniently litigated in Illinois than California, but whether it would be more convenient to litigate the California and Illinois actions separately or in a coordinated fashion." *Id.* at *2; *Cordis Corp.*, 682 F. Supp. at 1202 (S.D. Fla. 1987).

Likewise, in *Tingley Systems, Inc. v. Bay State HMO Management, Inc.*, the second-filed court granted defendant's motion to transfer to the first-filed forum even though defendant had not proven that its witnesses would be more inconvenienced than plaintiff's witnesses without a transfer. 833 F. Supp. 882, 886 (M.D. Fla. 1993). What defendant had established, however, was that "all parties and witnesses would be greatly burdened if all were required to travel

between two forums because the two related cases in which they were all involved were being tried in different states." *Id.* By transferring the second-filed action in the interest of justice, the Court held that all the parties would benefit because:

The two actions should be consolidated before one judge thereby promoting judicial efficiency, pretrial discovery could be conducted in a more orderly manner, witnesses could be saved the time and expense of appearing at trial in more than one court, duplicative litigation involving the filing of records in both courts could be avoided eliminating unnecessary expense and the possibility of inconsistent results could be avoided."

Id. at 888 (internal quotations omitted).

The facts supporting transfer are even more compelling here where sanofi-aventis has multiple suits pending in the District of Delaware that share the same claims and counterclaims concerning the '491 and '940 patents. In addition to the parallel action against Apotex, there are two other cases concerning infringement of the same patents by eight additional ANDAs referencing Uroxatral®, which will proceed regardless of what happens in this forum. Each of these actions has been assigned to the same Judge and Magistrate Judge. All answers and replies have been filed and the parties now await an initial scheduling order from the court. Plaintiffs expect that the Delaware court will coordinate pretrial activities in all three pending cases, and may consolidate all three actions for pretrial proceedings, in order to avoid duplicative discovery efforts and improve the efficiency of its docket.

By transferring this action for coordination with the Delaware cases, the Court will avoid duplicating pretrial activities, thus preserving judicial resources and reducing costs for the parties. For example, as the issues with respect to Plaintiffs' activities concerning the reference product Uroxatral® and the patents-in-suit are identical, transfer will avoid multiple depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the ANDA filers may seek discovery.

Likewise, transfer will avoid duplicative discovery disputes concerning these issues being adjudicated by separate courts. Moreover, transfer to Delaware will obviate the need for multiple courts to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, transfer will prevent potentially inconsistent rulings on critical issues such as the validity and enforceability of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. This factor is especially important with respect to the specialized *Markman* hearing courts must hold to construe the meaning of asserted claim terms as a matter of law, where inconsistent rulings could result in identical claim terms having different meaning for different defendants. *See Cordis*, 682 F. Supp. at 1202; *cf. MRL, LLC v. U.S. Robotics Corp.*, No. 02 C 2898, 2003 WL 685504, at *1-2 (N.D. Ill. Feb. 26, 2003) (denying motion to stay under an exception to the first-filed rule in favor of the second action where patentee's claims for infringement were pending before all accused infringers and would proceed regardless of whether the stay was granted); *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

C. Apotex's Unsupported Convenience And Congestion Arguments Are Substantially Outweighed By The Other Relevant Factors

Apotex argues that it would be more convenient for the witnesses and the parties to proceed in the Southern District of Florida, because Apotex Corp. is based in this District. Ex. 12 ¶ 10; Ex. 18 ¶ 19. As discussed above, Apotex is part of a multinational, billion dollar group of companies and has proceeded in Delaware in several other ANDA litigations without moving to transfer. In this case, as in the *Alere* and *Tingley* cases discussed above, any marginal convenience to Apotex of proceeding in Florida is vastly outweighed by the courts' and the

parties' interests in avoiding duplicative pretrial activities, in preventing potentially inconsistent rulings, and the inconvenience to the parties of having to proceed in two separate jurisdictions.

Apotex recently tried unsuccessfully to transfer an ANDA infringement action from the Southern District of Indiana to this forum even though there were no related actions pending in Indiana, let alone claims against 13 other defendants as in the case at bar. *See Alcon Mfg., Ltd. v. Apotex Inc.*, No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007). In *Alcon*, Apotex argued that (1) this forum was more convenient to Apotex and its witnesses and no less convenient for the plaintiff and (2) the interests of justice favored this forum because it had an interest in deciding local controversies and could conduct a more speedy trial.

The *Alcon* court rejected both of Apotex's arguments. First, the court found that Florida was not a more convenient forum because the parties were spread throughout the United States and internationally; thus, any financial burden of proceeding in the first-filed forum was insufficient to overcome the deference in plaintiff's choice of forum, even though it was not the plaintiff's home district. *Alcon*, 2007 WL 854026, at *2-3. Second, Apotex failed to show that transfer to Florida would be more convenient to the witnesses, as Apotex's development of its proposed generic product and preparation of the ANDA took place in Canada and plaintiffs' research and development of the patented product took place in Texas and Japan; thus, both parties' witnesses would have to travel to either the first- or second-filed forum, with the only apparent exception being the president of Apotex USA. *Id.*; *see also Abbott*, 2006 WL 850916, at *7 ("In a case where all of the witnesses of the [generic] defendant will be its employees, however, the location is not as important a factor as it would be if the witnesses were not under the control of the defendant."). Finally, the court rejected Apotex's interest of justice arguments as the suit was likely to affect consumers nationwide, not just in Florida, and because the case involved complex issues concerning patent infringement, it would likely take several years to

adjudicate, regardless of the venue. *Alcon*, 2007 WL 854026, at *4.

This case falls squarely within the *Alcon* court's rationale. Sanofi-aventis's witnesses and documents are likely to be found in Europe, New Jersey, and Pennsylvania, not Florida. As in *Alcon*, Apotex Inc., the Canadian corporation, is the holder of the ANDA, and it is likely that Canada is the situs of events such as preparation of that ANDA and its underlying research and development as well as the documents concerning and the witnesses with knowledge of those issues. Likewise, Apotex can make no showing this is a local dispute over which Florida has any specialized interest because Uroxatral® is sold throughout the country and Plaintiffs expect that Apotex will seek to market its products well beyond the borders of this forum as it has with its other generic products developed and manufactured abroad.

Apotex has indicated that the interest of a speedy trial necessitates proceeding in this Court. Ex. 13, Ex. 14. That argument failed in *Alcon* and should fail here as well. This is a complex litigation that will require the resolution of a variety of patent-specific issues, such as claim construction, infringement, and validity that will take a significant amount of time to adjudicate. Plaintiffs expect that Apotex will seek discovery on a wide-range of issues concerning the development of sanofi-aventis's inventions, patent prosecution, alleged prior art, and various marketing and regulatory activities. Many of the hundreds of thousands of potentially relevant documents are decades old and are located overseas where they must be reviewed in compliance with the European Union and member-state privacy directives prior to transport to the United States. Considering the number of inventors and other potentially relevant witnesses, including third parties, Plaintiffs expect the parties to conduct a large number of depositions, some of which may require Apotex to seek relief under the Hague Convention. Consequently, sanofi-aventis will ask Apotex to consent, or otherwise move the Court, to place this action on a Complex Track under Local Rule 16.1.A to ensure that the parties conduct

discovery in a fair and efficacious manner and fully develop their claims and defenses prior to trial.

And here of course, there is the additional factor that was not present in *Alcon*: that there are actions pending against 13 other defendants in the first-filed forum that must proceed regardless of where the present case is adjudicated.⁹

II. Alternatively, This Court Should Exercise Its Discretion To Stay This Action Pending The District Of Delaware's Adjudication Of Any Transfer Issues

If the Court does not transfer, sanofi-aventis respectfully requests that it stay the present action pending resolution of any transfer issues raised by Apotex in the first-filed Delaware action. It is well-settled that district courts have discretion to stay an action to give priority to first-filed parallel proceedings in another district. *See, e.g., Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 183-4 (1952); *Landis v. N. Am. Co.*, 299 U.S. 248 (1936); *Perkins v. Am. Nat. Ins. Co.*, 446 F. Supp. 2d 1350, 1353-54 (M.D. Ga. 2006). This power to stay actions is in the interest of "[w]ise judicial administration, giving regard to conservation of judicial resources and comprehensive disposition of litigation" *Kerotest*, 342 U.S. at 183; *Landis*, 299 U.S. at 254; *Lisa v. Mayorga*, 232 F. Supp. 2d 1325, 1326 (S.D. Fla. 2002). In deciding whether to order a stay, a district court should weigh the factors of judicial economy and balance the interests of the parties and the Court. *Id.*

The court in *PDL Biopharma, Inc. v. Sun Pharmaceutical Ind., Ltd.* was faced with a similar situation in which the patentee and NDA holder PDL moved to stay a second-filed so-called "protective action" based on the "first-filed" rule. ANDA filer and defendant Sun opposed

⁹ For the forgoing reasons, Plaintiffs expect that Apotex will likely fail in any motion to transfer the Delaware action to this forum. *See, e.g., Auto. Techs. Int'l, Inc. v. Amer. Honda Motor Co., Inc.*, No. 06-187 GMS, 2006 WL 3783477, at *2-3 (D. Del. Dec. 21, 2006) (denying motion to transfer where, *inter alia*, plaintiff had a rational and legitimate reason to sue defendants in the forum and noting that "a flight to Delaware is not an onerous task warranting transfer.").

the motion arguing that the "first-filed" rule should not apply because PDL was allegedly motivated by bad faith or forum shopping. Concerned that going forward with two identical actions simultaneously would waste scarce judicial resources and present the distinct possibility of conflicting rulings or judgments, the court overseeing the second-filed action held that application of the first-filed rule was appropriate and granted the stay. *PDL*, 2007 WL 2261386, at *2. The court rejected Sun's complaints of bad faith and forum shopping stating that:

Plaintiff filed the duplicative actions only because of the extraordinary time limit placed on the filing of suits under the Hatch-Waxman Act. Plaintiff correctly believed that Defendant would challenge personal jurisdiction in Plaintiff's preferred forum and concluded that, should a court in Plaintiff's preferred forum of the District of New Jersey find that jurisdiction was not appropriate there, the timing of the ruling could preclude Plaintiff from filing *any* action under the Act. These circumstances do not demonstrate bad faith or forum shopping on the part of Plaintiff. Furthermore, given the strict deadline and the potentially harsh outcome should Plaintiff's preferred forum dismiss the cause of action after the deadline, a consideration of the 'extraordinary circumstances' of the case weighs in favor of the stay.

Id. "[G]iven the unusual nature of ANDA claims and absent any guidance," the court found that plaintiff had satisfied its burden for a stay." *Id.*; see Ex. 19, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (staying second-filed action while jurisdictional issues were pending before the first-filed court).

The facts in the present case are identical in all relevant respects to those in *PDL*. Sanofi-aventis was forced by Apotex's temporary refusal to consent to jurisdiction in Delaware until after the 45-day period for bringing suit—and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights—to file a "protective action" in this District. Sanofi-aventis had a reasonable basis for concluding that Apotex is subject to jurisdiction in the District of Delaware, including Apotex's prior admissions in other ANDA litigations, which has been confirmed by Apotex's subsequent representations to the Delaware court that it will not challenge

jurisdiction. *See* Ex. 12. Apotex can hardly argue that sanofi-aventis's filing of parallel actions, or this motion, are motivated by bad faith or forum shopping. *See PDL*, 2007 WL 2261386, at *2; *see also Abbott*, 2006 WL 850916, at *8.

As in *PDL*, balancing the interests of the parties favors a stay of this action. Requiring the parties to litigate the same issues in this action in parallel to the first-filed Delaware actions is likely to lead to significant duplication of effort and expense, as discussed above with respect to transfer. There is no prejudice to weigh against these interests as the parties will continue to litigate their claims and defenses in the District of Delaware. Moreover, in the unlikely event that Apotex successfully moves the Delaware court to transfer the first-filed action here, the Court can immediately lift the stay and proceed in this case.

CONCLUSION

For all the foregoing reasons sanofi-aventis requests that the Court transfer this action to the District of Delaware. In the alternative, sanofi-aventis requests that the Courts stay this action until the District of Delaware adjudicates any motion to transfer brought by Apotex.

Dated: January 8, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 8, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

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SERVICE LIST

SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL

Case No.: 07-61800-CIV-Moreno/Simonton

**United States District Court
Southern District of Florida
(Miami Division)**

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VIA CM/ECF

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

**[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION TO TRANSFER OR STAY**

THIS CAUSE is before the Court on Plaintiffs' Motion to Transfer or Stay, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that:

- ☐ The above-captioned proceeding is hereby transferred to the United States District Court for the District of Delaware.

☐ The above-caption proceeding is hereby stayed until the District of Delaware adjudicates any motion to transfer brought by Defendants.
- The Parties are hereby authorized to take action consistent with this Court's ruling.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of January, 2008.

Honorable Federico A. Moreno
United States District Court Judge

EXHIBIT Q

**BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

**IN RE ALFUZOSIN HYDROCHLORIDE
PATENT LITIGATION**

MDL Docket No.

**PLAINTIFFS' MOTION TO TRANSFER
AND CONSOLIDATE FOR PRETRIAL PROCEEDINGS**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions, *Sanofi-*

aventis et al. v. Actavis South Atlantic LLC et al., No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT), pending in that District. A list of the four pending actions identifying all parties and the presiding judges is attached hereto as the Schedule of Actions.

In support of transfer and consolidation, sanofi-aventis avers the following, more fully set forth in the accompanying brief in support of this motion:

1. All four actions for which transfer and consolidation are proposed involve the infringement, validity and enforceability of the same two patents: U.S. Patent No. 4,661,491 ("the '491 patent") titled "Alfuzosine Compositions and Use" and U.S. Patent 6,149,940 ("the '940 patent") titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate." Sanofi-aventis is the current assignee of the '491 patent and a co-assignee, with Jagotec AG, of the '940 patent.

2. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets. The '491 and '940 patents cover this product, and have been submitted to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) as patents that claim an alfuzosin hydrochloride product. Based on that submission, both patents have been listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

3. In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed

generic alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents.

4. As part of each ANDA, the submitting entity or entities included one or more allegations under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product. Each Paragraph IV Certification sets out the grounds on which the submitting entity or entities allege that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product defined by the ANDA. In many cases, the grounds on which the submitting entity or entities alleged that the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic product were identical or very similar. For example, each Paragraph IV Certification against the '491 patent alleges that the claims are invalid as obvious over varying combination of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. And in each Paragraph IV Certification alleging non-infringement of the '940 patent, the ANDA filer argues that there is no infringement because the proposed generic product does not meet the '940 patent's layer limitation.

5. Apotex Inc. sent sanofi-aventis a Paragraph IV Certification, dated August 14, 2007, with respect to the '940 patent. Apotex Inc. then sent sanofi-aventis a second Paragraph IV Certification, dated October 25, 2007, with respect to the '491 patent.

6. Each of these filings was an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

7. Given that personal jurisdiction could be exercised against all 15 potential defendants in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in the United States District Court for the District of Delaware against the 13 defendants it elected to sue at that time¹ for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.²

8. The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are: Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

9. In response to Apotex Inc.'s second Paragraph IV Certification, dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex Inc. and Apotex Corp. (collectively "Apotex") in Delaware on December 6, 2007 for infringement of the '491 patent. That action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge.

¹ At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product.

² In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940 patent alone against four additional defendants.

10. The three Delaware actions are in their early stages. All 15 defendants, including Apotex, have filed their answers and counterclaims and sanofi-aventis has filed all of its replies. In its answer, Apotex conceded that jurisdiction and venue were proper in Delaware. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay. Sanofi-aventis filed its opposition brief on January 31, 2008. As of the date of this application, Apotex has not served its rely brief and no decision has been issued.

11. Under the Hatch-Waxman Act, a patentee has a strict statutory 45-day window in which to file an infringement action after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired.

12. Although sanofi-aventis believed that the District of Delaware could properly exercise personal jurisdiction over all 15 defendants, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct, representations made in their respective Paragraph IV Certification letters, and/or refusals to consent to jurisdiction in Delaware.

13. The District of Delaware can properly exercise personal jurisdiction over all defendants. However, given the uncertain consequences surrounding the potential challenges to personal jurisdiction in Delaware, sanofi-aventis had no choice but to bring second-filed actions

in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. Sanofi-aventis brought such second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007³ and against Apotex on December 10, 2007.

14. Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware.

15. On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's Complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's Complaint in the Delaware action against Apotex, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. The Florida action is also at an early stage.⁴

16. One business day after answering the Florida Complaint, on January 2, 2008, Apotex answered the Complaint in the first-filed Delaware action – conceding that jurisdiction

³ Sanofi-aventis commenced the following four second-filed actions, all of which have been dismissed: (1) *Sanofi-aventis et al. v. Torrent Pharma Inc. et al.*, Case No. 1:07-cv-969 (W.D. Mich.) (filed September 27, 2007; dismissed October 18, 2007); (2) *Sanofi-aventis et al. v. Mylan Pharmaceuticals Inc.*, Civil Action No. 1:07CV139 IMK (N.D.W.V.) (filed October 5, 2007; dismissed October 18, 2007); (3) *Sanofi-aventis et al. v. Sun Pharmaceutical Industries, Inc. et al.*, Case: 2:07-cv-14355 (E.D. Mich.) (filed October 12, 2007; dismissed December 3, 2007); and (4) *Sanofi-aventis et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 07 CV 5807 (BMM) (N.D. Ill.) (filed October 12, 2007; dismissed January 17, 2008).

⁴ The Florida action has not progressed significantly further than the Delaware actions despite the fact that the court has issued a scheduling order. Notably no significant discovery has occurred: Apotex has served its Rule 26(a) Initial Disclosures—insufficient in that it discloses only one individual and one document category at an undisclosed location—and a set of 35 document requests. Sanofi-aventis has not served or responded to any discovery requests. Neither party has produced any documents, nor has a protective order been entered.

and venue were proper in Delaware – and asserted the same counterclaims. Sanofi-aventis filed its reply to Apotex's counterclaims in Delaware on January 3, 2008.

17. Sanofi-aventis moved to transfer the Florida action to Delaware or to stay the action pending resolution of the venue issues in the first-filed Delaware action on January 8, 2008 in the interests of judicial economy and efficiency and the convenience of the parties and witnesses. Apotex filed its opposition brief on January 28, 2008. As of the date of this application, sanofi-aventis has not served its reply brief and no decision has been issued.

18. The three Delaware actions and the Florida action described above all focus on the infringement, validity, enforceability, claim construction and scope of the same sanofi-aventis patent(s), the '491 patent and/or the '940 patent. Thus, these cases involve one or more common questions of fact. 28 U.S.C. § 1407(a).

19. Transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, will be the most convenient for the parties. 28 U.S.C. § 1407(a).

20. Additionally, transfer of the Florida action to the District of Delaware, and consolidation of pretrial proceedings with the three pending actions in the District of Delaware, is in the interests of judicial economy in that it will promote just and efficient resolution of the cases. 28 U.S.C. § 1407(a). Transfer will also promote the certainty of patent rights and prevent duplicative actions in multiple districts thereby avoiding the possibility of inconsistent rulings.

21. Sanofi-aventis respectfully requests that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

This motion is based on the BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407, the pleading and papers on file herein, and such other matters as may be presented to the Panel at the time of hearing.

Dated: February 1, 2008

Respectfully submitted,

A handwritten signature in cursive script, reading "Gerald J. Flattmann, Jr." followed by a large, stylized initial "AF".

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Before the Judicial Panel on Multidistrict Litigation
MDL-_____ - In re Alfuzosin Patent Litigation

SCHEDULE OF ACTIONS

Case Captions	Court	Civil Action No.	Judge
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC Defendants: Actavis South Atlantic LLC; Aurobindo Pharma Ltd.; Aurobindo Pharma USA Inc.; Mylan Pharmaceuticals Inc.; Par Pharmaceutical, Inc.; Ranbaxy Inc.; Ranbaxy Laboratories Limited; Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Torrent Pharma Inc.; and Torrent Pharmaceuticals Limited	D. Delaware	07-572	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC Defendant: Barr Laboratories, Inc.	D. Delaware	07-574	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC Defendants: Apotex Inc. and Apotex Corp.	D. Delaware	07-792	Gregory M. Sleet
Plaintiffs: Sanofi-aventis and sanofi-aventis U.S. LLC Defendants: Apotex Inc. and Apotex Corp.	S.D. Florida Miami Division	07-61800	Federico A. Moreno

**BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

**IN RE ALFUZOSIN HYDROCHLORIDE
PATENT LITIGATION**

MDL Docket No.

**BRIEF IN SUPPORT OF PLAINTIFFS' MOTION
FOR TRANSFER OF ACTION PURSUANT TO 28 U.S.C. § 1407**

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I. INTRODUCTION

Sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby respectfully move the Judicial Panel on Multidistrict Litigation ("the Panel") for an order: (a) transferring the civil action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON (S.D. Fla.), pending in the United States District Court for the Southern District of Florida to the District of Delaware; and (b) consolidating that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions against 13 defendants that have been pending in Delaware since September 2007, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT).¹

Transfer and consolidation in this manner are warranted because all four actions involve numerous questions of fact and law concerning sanofi-aventis's claims that the 15 defendants each infringe one or both of sanofi-aventis's patents-in-suit, and because the convenience of the parties and witnesses and the just and efficient conduct of the actions will best be promoted by coordinated proceedings in the District of Delaware.

II. BACKGROUND

Sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. Sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in the state of New Jersey.

¹ The names of all parties to the pending actions, and the assigned judges, are set out in the Schedule of Actions attached to Plaintiffs' motion.

Sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." (Ex. A). It is also a current assignee of United States Patent No. 6,149,940 ("the '940 patent"), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."² (Ex. B). Sanofi-aventis U.S. LLC sells alfuzosin hydrochloride 10 mg extended release tablets, covered by both the '491 and '940 patents, throughout the United States for the treatment of the signs and symptoms of benign prostatic hyperplasia under the brand name Uroxatral®. Sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287 relating to Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets and in conjunction with that NDA, submitted both the '491 and '940 patents to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(1) for listing in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book").

A. In the Summer of 2007, Nine Abbreviated New Drug Applications Were Filed Seeking FDA Approval to Market Copies of Sanofi-aventis's Uroxatral® Brand Alfuzosin Hydrochloride Product

In the Summer of 2007, nine separate Abbreviated New Drug Applications ("ANDAs") for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Each of these ANDAs seeks the FDA approval necessary for the submitting entity or entities to engage in the commercial manufacture, use and sale of generic copies of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the submitting entity or entities included an allegation under § 505(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the claims of the '491 patent and/or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of

² Jagotec AG is also a current assignee of the '940 patent. Sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent.

the proposed generic products and the grounds for those allegations. Each of these filings was an act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). The commercialization of the generic ANDA drug products would be further acts of infringement. *See* 35 U.S.C. § 271(a), (b) and (c).

B. Because Personal Jurisdiction Was Available Against All Defendants In The District Of Delaware, Sanofi-aventis First Filed Actions In That District Against Each Of The 15 Defendants

Because personal jurisdiction exists over all of the entities involved in the submission of the infringing ANDAs and Paragraph IV Certifications in the District of Delaware, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) (the "Actavis Dkt.") and 07-574 (GMS) (MPT) (the "Barr Dkt.") on September 21, 2007 in the United States District Court for the District of Delaware against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective Paragraph IV Certifications.³ *See* Complaints (Actavis Dkt. 1; Barr Dkt. 1).⁴ At the time of the filing the first two Delaware complaints, Apotex's ANDA only included a Paragraph IV Certification against the '940 patent. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis did not file an action against Apotex for infringement of the '940 patent. Sanofi-aventis then received a second Paragraph IV Certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. In response, sanofi-aventis commenced the first-filed action, Civil Action No. 07-792 (GMS) (MPT) (the "Apotex DE Dkt."), against Apotex in Delaware on December 6, 2007 for infringement of the '491 patent.

³ In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940 patent alone against four additional defendants.

⁴ The 13 defendants named in the Complaints filed in Delaware on September 21, 2007 are Actavis South Atlantic LLC ("Actavis"), Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc. (collectively "Aurobindo"), Barr Laboratories, Inc., Mylan Pharmaceuticals Inc. ("Mylan"), Par Pharmaceutical, Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Sun Pharmaceutical Industries Ltd. (collectively "Sun"), Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. (collectively "Torrent").

See Complaint (Apotex DE Dkt. 1). On January 2, 2008, Apotex answered the complaint and conceded that jurisdiction and venue were proper in Delaware:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." *See* Apotex Delaware Answer ¶ 7 (Apotex DE Dkt. 7).
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it" *Id.* ¶ 8.
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action" *Id.* ¶ 10.

In each of the three first-filed Delaware actions, sanofi-aventis alleges infringement of either the '491 patent and/or the '940 patent based on the filing of the ANDAs and any subsequent commercialization. All three actions are designated as related cases and are proceeding before the same Judge and the same Magistrate Judge. The actions are in their early stages. As of January 7, 2008, all 15 defendants had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The parties now await an order setting the Rule 26(f) scheduling conference. On January 24, 2008, Apotex served a motion to transfer or stay the action against it. Sanofi-aventis filed its opposition brief on January 31, 2008. Apotex has not yet served its reply brief and no decision has been issued.

C. Because A Number Of Defendants Threatened To Challenge Personal Jurisdiction In The District Of Delaware, Sanofi-aventis Was Forced To File Five Parallel Actions In The Southern District Of Florida, The Northern District Of Illinois, The Eastern District Of Michigan, The Western District Of Michigan And The Northern District Of West Virginia

To litigate under the protections of the Hatch-Waxman Act, sanofi-aventis was required to file an action against each ANDA submitting party or parties within forty-five days of receiving notice of the Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Abbott*

Labs. v. Mylan Pharm., Inc., No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006).⁵

Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in Delaware and with respect to Apotex by its December 6, 2007 complaint in Delaware. Prior to filing the Delaware actions, however, sanofi-aventis was concerned that Apotex, Aurobindo, Mylan, Sun, and/or Torrent would contest personal jurisdiction in Delaware based on prior litigation conduct and/or representations made in their respective Paragraph IV Certification letters. Sanofi-aventis's concerns appeared justified when Apotex, Aurobindo, Mylan, Sun, and Torrent refused to consent to jurisdiction in Delaware during sanofi-aventis's strict 45-day window in which to bring suit.

The law remains unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See PDL BioPharma, Inc. v. Sun Pharm. Inds., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8. The consequences of losing the protections of the Hatch-Waxman Act, however, are clear and are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) ("[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate

⁵ A compendium of unpublished cases cited herein is attached as Ex. C.

the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market."). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

The District of Delaware can properly exercise personal jurisdiction over all 15 defendants in the three first-filed Delaware actions. Given the uncertain consequences surrounding the unlikely, but possible dismissal of any defendant from one of the Delaware actions, sanofi-aventis had no choice but to bring second-filed actions in the jurisdictions in which sanofi-aventis was certain Apotex, Aurobindo, Mylan, Sun, and Torrent would not contest personal jurisdiction. As a result, sanofi-aventis brought second-filed actions within the statutory 45-day window against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007 and against Apotex on December 10, 2007. The second-filed suits against Aurobindo, Mylan, Sun, and Torrent have each been dismissed, leaving Apotex as the lone outstanding second-filed suit.⁶

1. Sanofi-aventis Filed A Second-Filed Action In The Southern District Of Florida Against Apotex Because Sanofi-aventis Knew Apotex Would Not Contest Personal Jurisdiction In That District

Despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware,⁷ Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. (*See* Ex. G,

⁶ The docket sheets for the second-filed suits against Aurobindo, Mylan, Sun, and Torrent are attached as Ex. D.

⁷ On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. *See* Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al*. No. Civ. 07-204-SLR at 3-4; Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. (Ex. E). In fact, Apotex has also availed itself of the Delaware court as a plaintiff. *See* Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4. (Ex. F).

12/06/07 W. Vuk ltr to B. Sherman.) It was only after that period ran that Apotex represented that it would not contest jurisdiction in Delaware. (Ex. H, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo.) Thus, On December 10, 2007, sanofi-aventis commenced Civil Action No. 07-61800-CIV-MORENO/SIMONTON (the "Apotex FL Dkt.") in the Southern District of Florida against Apotex ("the Florida action"). Sanofi-aventis's complaint in the Florida action replicated the allegations made against Apotex in sanofi-aventis's complaint in the first-filed Delaware action, including infringement of the '491 patent by the filing of Apotex Inc.'s ANDA, which Apotex Corp. participated in, contributed to, aided, abetted and/or induced. *See* Florida Complaint (Apotex FL Dkt. 1).

Similar to the Delaware actions, the Florida action is in its early stages.⁸ Sanofi-aventis did not serve its Complaint, yet Apotex filed an Answer and Counterclaims on December 28, 2007; one business day before Apotex answered the Delaware complaint. Sanofi-aventis filed its Reply to Apotex's counterclaims on January 17, 2008 and, prior to filing that reply, on January, 8, 2008, sanofi-aventis moved to transfer the Florida action to Delaware or to stay the Florida action pending the disposition of any transfer issues raised by Apotex in Delaware. Apotex filed its opposition brief on January 28, 2008. Sanofi-aventis has not yet served its reply brief and no decision has been issued. In summary, sanofi-aventis argued that transfer or stay of the Florida action is appropriate in the interests of judicial economy and efficiency to avoid the need for two federal courts to assess the same issues thereby leading to a waste of time and resources on

⁸ While the Florida court has issued a scheduling order setting the trial date for October 2008, the action has not truly progressed significantly further than the Delaware actions. The parties have not had their initial case management conference with the judge and Plaintiffs have asked the Florida court to set the trial for June 2009 in its status report filed in anticipation of that conference. Sanofi-aventis expects that the dates for discovery and trial will have to be pushed back to ensure that the parties' claims and defenses are fully-developed in a fair and efficacious manner. Notably no significant discovery has occurred: Rule 26(a) Initial Disclosures have been exchanged and Apotex has served its document requests; sanofi-aventis has not served or responded to any discovery requests; and neither party has produced any documents, nor has a protective order been entered.

duplicative discovery and other pretrial proceedings, potentially inconsistent rulings on issues that impact the certainty of patent rights, as well as great inconvenience to the parties and witnesses which will have to proceed in two separate districts.

III. SUMMARY OF THE ARGUMENT

Each of the four pending actions involves issues that are not just common, but are essentially identical. For example, the same sanofi-aventis patents are at the core of all four pending actions. Moreover, all defendants are trying to make generic versions of the same product and contend that the patents they certified against are either not infringed, invalid over prior art and/or unenforceable based upon essentially the same arguments. Thus, the claims, defenses and counterclaims in all four actions will involve consideration of the same documents, technology, testimony, and legal theories. Centralization is necessary here to eliminate duplicative proceedings and discovery, prevent inconsistent pretrial rulings and conserve judicial resources. Because none of the four actions is near trial, and no significant discovery has taken place, consolidation and centralization is favored and should be ordered now, before substantial pretrial proceedings take place.

IV. ARGUMENT

A. The Applicable Standard

Section 1407(a) of Title 28 of the United States Code provides:

When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.

28 U.S.C. § 1407. Patent cases, as noted by Congress, are particularly appropriate for transfer and consolidation. *See* H.R. No. 90-1130, 1st Sess. (1968).

B. Sanofi-aventis's Four Actions Involve Multiple Common Questions Of Fact And Law

Section 1407 requires consideration of whether the actions sought to be consolidated involve common questions of fact, whether consolidation will promote a just and efficient resolution of the parties' dispute, and whether transfer and consolidation will best serve the convenience of the parties and witnesses. *See* 28 U.S.C. § 1407; *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007) ("[W]e find that these three actions involve common questions of fact, and that centralization under Section 1407 in the [first-filed District] will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."). Because the present situation with respect to sanofi-aventis's four actions meets each of these criteria, as described below, transfer and consolidation is warranted.

Sanofi-aventis's four pending actions satisfy the first requirement of Section 1407(a) by having numerous questions of fact and law in common. Although 28 U.S.C. § 1407(a) is phrased in terms of common questions of fact, the Panel also considers common questions of law when applying this standard. *See, e.g., In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d 1361, 1361 (J.P.M.L. 2005) (stating that, because all three actions sought to be consolidated involved claims that generic products infringed one or more of the same patents, "[t]he actions can thus be expected to share factual and legal questions . . .").

The Panel's decision in *In re Desloratadine* is instructive here. 502 F. Supp. 2d at 1355. In that case, the patentee filed a complaint alleging patent infringement based upon the submission of ANDAs to the FDA against 21 defendants in the District of New Jersey. *Id.* Several defendants threatened to, and eventually did, challenge jurisdiction; thus the patentee

was forced to bring second-filed actions in other districts. The patentee moved the Panel to consolidate the actions in the first-filed forum where the majority of defendants already were in front of the court. Only two defendants objected to the consolidation, arguing that it would delay the resolution of the second-filed action—which was only proceeding against them. The Panel ordered consolidation and transferred the cases to the first-filed court, noting that "assigning the present actions to a single judge who can formulate a pretrial program that ensures that all pretrial proceedings will be conducted in a just and expeditious manner." *Id.* Here, 15 defendants are in front the District of Delaware, the first-filed court, and only Apotex is attempting to proceed in a different forum. Consolidation in front of the first-filed court—the District of Delaware—here is even more compelling than in *In re Desloratadine* because Apotex has consented to jurisdiction and admitted that venue is proper in Delaware.

"[T]ransfer under Section 1407 does not require a complete identity or even a majority of common factual or legal issues as a prerequisite to transfer." *See In re Acacia Media Techs. Corp. Patent Litig.*, 360 F. Supp. 2d 1377, 1379 (J.P.M.L. 2005). Here, however, the common issues of law and fact will predominate because all four actions involve the '491 patent and/or the '940 patent and proposed generic versions of the same Uroxatral® brand product, and many of the defendants have raised the same defenses and counterclaims. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations where "[i]n each action [the patentee] has asserted that a proposed generic product infringes its patent...."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361 (ordering consolidation of three patent infringement actions where "[a]ll three actions involve one or more patents related to...[the branded pharmaceutical] product sold by [the plaintiff]."). The defendants may have slightly different formulations or base their obviousness arguments on different combinations of

prior art, but that is not justification for denying a request for transfer and consolidation. *In re Omeprazole Patent Litig.*, MDL No. 1291, 1999 U.S. Dist. LEXIS 12589, *2 (J.P.M.L. Aug. 12, 1999) ("Several opposing defendants argue that centralization is not warranted in light of the fact that issues of patent infringement are unique in each action, because each defendant's allegedly infringing formulation is different. We disagree.").

Unless the four actions are consolidated for all pretrial purposes, both the Delaware and Florida courts will be required to independently conduct the same complex analyses relating to claim construction, infringement, and patent validity issues. *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (noting that related patent infringement actions share factual and legal issues concerning validity and related questions.); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361 (same). For example, both courts would be required to construe terms from the claims of both patents. Thus, each court would have to consider the language of the claims, analyze the specification and study the file histories of both patents. These common considerations warrant consolidation. *Id.* (granting order to transfer and consolidate where multiple actions alleged infringement of patent by generic pharmaceutical products).

Similarly, because the validity of both patents are challenged in each case, both courts may be required to address the state of the science and the knowledge of one of ordinary skill in the art at the relevant time, and the scope and content of each prior art reference asserted with respect to each asserted claim from the patents. Again, these factors warrant transfer and consolidation. *See, e.g., In re Smith Patent Litig.*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976) (holding that common issues of validity "justify transfer."); *In re Nabumetone Patent Litig.*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (J.P.M.L. Sept. 2, 1998) (consolidating four actions based on common issue of one patent's validity); *In re Gabapentin Patent Litig.*, MDL

No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (J.P.M.L. Feb. 5, 2001) (ordering transfer where four actions involved "validity of the same complex pharmaceutical patent").

Here, a more specific common issue stems from the fact that each ANDA filer, except Barr Laboratories, asserts the same non-infringement argument in their '940 patent Paragraph IV Certifications, namely that the proposed generic products do not meet the '940 patent's layer limitation. Absent centralization, both courts will be required to assess this claim construction issue in light of the language of the claims, specification and file history of the '940 patent, and will be required to consider the same extrinsic evidence such as expert testimony. Additionally, the common asserted defense of obviousness with respect to the '491 patent raised by every ANDA filer—including Apotex—that filed a '491 patent Paragraph IV Certification, also presents common issues. Each ANDA filer argues that that the '491 patent is invalid as obvious over combinations of art that they allege establishes that alfuzosin was known to be an alpha-adrenergic blocker and it was known to use alpha-adrenergic blockers to treat prostate problems. Accordingly, it is clear that the four actions will involve common issues of obviousness with respect to the '491 patent and, absent centralization, both judges will be required to learn the technology behind the '491 patent and the state of the art in a complex pharmaceutical field involving technology, research and development that dates back nearly 30 years.

In sum, given the numerous questions of fact and law that are common to all four actions, transfer and consolidation under Section 1407(a) is appropriate and should be granted. *See, e.g., In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355; *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1361; *In re Acacia Media Techs. Corp.*, 360 F. Supp. 2d at 1379.

C. Consolidation Will Promote A Just And Efficient Resolution Of Sanofi-aventis's Actions

Transfer and consolidation of the actions will also promote the just and efficient conduct of the actions, satisfying the second requirement of Section 1407(a). As the Supreme Court noted, "Patent infringement litigation often raises difficult technical issues that are unfamiliar to the average trial judge." *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank.*, 527 U.S. 627, 651 (1999). Given the complexity of the pending actions and the numerous overlapping factual and legal questions stemming from the issues of infringement and validity of both the '491 and '940 patents, consolidation of all pretrial proceedings will best promote the interests of justice and efficiency. *Eason v. Linden Avionics, Inc.*, 706 F. Supp. 311, 330 (D.N.J. 1989) ("[L]itigation of related claims in the same tribunal is strongly favored because 'it facilitates efficient, economical and expeditious pretrial proceedings and discovery and avoids [duplicative] litigation and inconsistent results.'").

First, consolidation will promote judicial economy because only one judge will be required to understand the complexities of the technology involved in the patents-in-suit and the prior art for the purposes of all pretrial proceedings. Without consolidation, each judge would not only need to learn the science underlying the patented method of treatment, the patented formulations, the prior art, and the prosecution histories of the '491 and the '940 patents, but also apply that understanding in construing the asserted patent claims and ruling on pretrial motions. The complexity of the issues coupled with the number of common defenses and counterclaims make these actions ripe for transfer and consolidation. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (ordering consolidation of three ANDA litigations and stating "[c]entralization under Section 1407 will eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim

construction; and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same).

Second, consolidation will prevent inconsistent pretrial rulings. For example, consolidation will prevent inconsistent claim construction rulings. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (holding that claim construction is a matter of law for the judge to decide). To determine whether a patent claim is infringed or invalid over a prior art reference, a court must first construe the claim as a matter of law. To do this, courts typically conduct a *Markman* hearing, a formal procedure in which the parties present evidence and argument as to the meaning of disputed terms in the asserted patent claims. In this case, claim construction in each action is likely to be complicated and time-consuming. Without consolidation, each court will have to engage in its own claim construction process, which will not only waste judicial resources, but will also present the potential for inconsistent rulings. This is precisely the scenario that Section 1407 was designed to avoid. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 (stating that centralization will "prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claim construction;"); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same).

Third, consolidation will result in a more efficient discovery schedule for the parties and the court, avoiding duplicative written discovery, document productions, discovery motions and the like. Given that the same patents are at issue in all four of sanofi-aventis's actions, that the defendants' products are all generic versions of the same Uroxatral® brand product, and the substantial overlap of the defenses in each action, the scope of discovery will substantially overlap in the four actions. *In re Burke, Inc., Pers. Mobility Vehicle Patent Litig.*, MDL No. 809, 1989 U.S. Dist. LEXIS 13662, at *2 (J.P.M.L. Aug. 22, 1989) (consolidating infringement

actions involving a single patent "to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary").

Finally, consolidation is particularly desirable here because all four actions are in their early stages. As noted above, the parties have not exchanged any discovery, although Apotex has served a set of document requests, and no court has construed the claims or received claim construction briefs from the parties.

D. The Panel's Transfer And Consolidation Of Sanofi-aventis's Actions Will Best Serve The Convenience Of The Parties And Witnesses

Transfer and consolidation of the actions will be most convenient for the parties and witnesses. Consolidation will serve as a cost-saving measure to the parties by avoiding duplicative discovery and other pretrial burdens in relation to common issues. *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355 ("[c]entralization under Section 1407 will eliminate duplicative discovery... and conserve the resources of the parties, their counsel and the judiciary."); *In re Rivastigmine Patent Litig.*, 360 F. Supp. 2d at 1362 (same); *In re Inter-Op Hip Prosthesis Prods. Liab. Litig.*, 149 F. Supp. 2d 931, 933 (J.P.M.L. 2001) (explaining that centralization would effectuate "an overall savings of cost and a minimum of inconvenience to all concerned" with the pretrial activities). Transfer and consolidation will "ensure that discovery will transpire but once and, at the same time, will also streamline the rest of the pretrial process through the involvement and supervision of only a single judge in a single district." *In re Celotex Corp. "Technifoam" Prods. Liab. Litig.*, 68 F.R.D. 502, 504 (J.P.M.L. 1975).

If discovery were to proceed in two courts in parallel, sanofi-aventis would be required to seek and provide the same discovery twice. Sanofi-aventis would also be forced to litigate claim construction issues and go through the summary judgment process twice. That would not

promote convenience, especially if the Florida action proceeds on a different schedule than the Delaware actions where all defendants, other than Apotex, would have to continue to participate.

Transfer and consolidation will also avoid subjecting witnesses to multiple depositions on identical subject matter. *See In re M3Power Razor Sys. Mktg. & Sales Prac. Litig.*, 398 F. Supp. 2d 1363, 1365 (J.P.M.L. 2004) ("Section 1407 will offer the benefit of placing all actions in this docket before a single judge who can structure pretrial proceedings to accommodate all parties' legitimate discovery needs while ensuring that common party and witnesses are not subjected to discovery demands that duplicate activity that will or has occurred in other actions."). Sanofi-aventis expects that the parties will require at least 100 fact depositions.⁹ Many of the witnesses: (a) are located outside of the United States and some may not fall within the power of the federal courts; (b) are not fluent in English and will require interpreters; and (c) may have travel restrictions due to health issues and age-related complications that may impact their ability to travel for deposition. These factors will lengthen both the individual depositions themselves as well as the time necessary to coordinate and complete all fact deposition discovery. The burden on the witnesses of being subjected to two depositions, that may require multiple days of testimony, compels the consolidation of these four actions.

These advantages outweigh any minor burdens placed on the parties by consolidation. For example, it is unlikely that Apotex—which conceded that jurisdiction and venue were proper in Delaware—can demonstrate any significant prejudice as a result of the transfer and consolidation of the actions for pretrial proceedings in the District of Delaware. Indeed, this is especially true given that Apotex admitted that its lone knowledgeable employee and sole

⁹ It is likely that the parties will seek deposition testimony from the eight inventors named on the patents and a variety of other witnesses with knowledge of the alleged prior art, Uroxatral®, the proposed generic product, including the decision to file, the preparation and submission of each of the nine ANDAs, the research, development and formulation pertaining to the proposed generic products, and marketing and regulatory issues.

category of documents related to its claims and defenses are located in Canada, not Florida. *See* Initial Disclosures (Ex. I). Furthermore, both Apotex Inc. and Apotex Corp. have litigated in the Delaware court on at least five separate occasions. (Ex. E, F). In any case, because consolidation by the Panel would be for pretrial proceedings only, the consolidation will not necessarily require Apotex's witnesses to travel to Delaware for depositions or otherwise. *See, e.g. In re MLR, LLC, Patent Litig.*, 269 F. Supp. 2d 1380, 1381 (J.P.M.L. 2003).

Defendants' counsel would also not be adversely affected by consolidation. Apotex's lead counsel is located in Chicago and would have to travel if the action proceeded in Delaware or Florida. In any case, the burden on counsel is of little importance when compared to the significant burden of duplicative discovery responsibilities on sanofi-aventis and its witnesses, including multiple depositions of the same witnesses on the same topics. Furthermore, any burden on counsel can be easily overcome. *See, e.g., In re Cygnus Telecommunications Tech., LLC*, 177 F. Supp. 2d 1375, 1376 (J.P.M.L. 2001) ("the judicious use of liaison counsel and lead counsel will eliminate the need for most counsel ever to travel to the transferee district.").

In sum, any burden on the defendants would be minimal and would be far outweighed by the prejudice to sanofi-aventis and its witnesses if required to conduct parallel litigation in two separate forums. Accordingly, this factor weighs strongly in favor of transfer and consolidation.

E. Coordinated Pretrial Proceedings Should Proceed In The United States District Court For The District Of Delaware

Once the Panel determines that centralization within a single forum is appropriate, the actions should be consolidated in the district that will best "serve the convenience of the parties and witnesses and promote the just and efficient conduct of th[e] litigation." *See In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has previously recognized the advantage of consolidating cases in a district where one of the actions is pending. *See, e.g., In re*

Mirtazapine Patent Litig., 199 F. Supp. 2d 1380, 1381 (J.P.M.L. 2002) (transferring to a district where several actions were pending). Further, the Panel has stated that it is appropriate that the action be consolidated in the district where the most broadly-based and earliest-filed action is pending. *See In re Regents of Univ. of California*, 964 F.2d 1128, 1136 (Fed. Cir. 1992).

In view of these policies, the District of Delaware is the only forum situated to promote the interests of justice, efficiency, and convenience to all of the parties. The Delaware actions were earliest filed with two of the suits being filed against 13 defendants nearly three months before the Florida action was filed against just two related defendants. The first-filed Delaware actions also encompass all 15 defendants, making them the most broadly-based of the actions. *Id.* Because sanofi-aventis's first-filed Delaware actions are already pending against all defendants in that district, it is most efficient to keep the cases there. Again, Apotex has conceded that jurisdiction and venue are proper in Delaware and has failed to identify any witnesses or documents relating to sanofi-aventis's action against Apotex that are located in Florida. These factors weigh considerably in favor of transfer of the Florida action to the District of Delaware for consolidation with the first-filed Delaware actions.

F. Consolidating The Actions For Pretrial Proceedings Would Serve The Purposes Of The Hatch-Waxman Act

Transfer and consolidation in this action is also consistent with the purposes of the Hatch-Waxman Act. Indeed, the Panel has recognized that "actions involving the validity of pharmaceutical patents, in which the entry of generic versions of drugs into the market is also at issue, are well-suited for transfer under Section 1407." *In re Desloratadine Patent Litig.*, 502 F. Supp. 2d at 1355. The Panel has also noted that transfer and consolidation under Section 1407 is consistent with the "expedited" nature of ANDA litigation under the Hatch-Waxman Act. *Id.* (ordering transfer and consolidation of ANDA litigations and stating that the transfer "will have

the salutary effect of assigning the present actions to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious manner."); *see also In re Gabapentin*, MDL No. 1384, 2001 U.S. Dist. LEXIS 1726, at *2 (transferring and consolidating ANDA actions and dismissing as "misplaced" the defendants' argument that "transfer will engender further delays in a litigation in which time is of the essence"); *In re Nabumetone*, MDL No. 1238, 1998 U.S. Dist. LEXIS 13735, at *2 (same).

Further, consolidation of the pretrial proceedings against all defendants will ensure that the intent of Congress in enacting the Hatch-Waxman Act is not frustrated because all defendants will be placed on an equal footing in their bid to market a generic version of sanofi-aventis's Uroxatral® brand alfuzosin hydrochloride product. The Hatch-Waxman Act provides 180 days of exclusivity against competing generic manufacturers to the first filer of an ANDA that challenges the validity, enforceability or infringement of a patent listed in connection with a pioneer drug. 21 U.S.C. § 355(j)(5)(B)(iv). In the present case, each of the nine separate ANDAs seeking approval to market a copy of sanofi-aventis's Uroxatral® brand drug product was filed on the same day, and thus each of the ANDA filers is a "first-filer" eligible for the 180 day exclusivity. In these circumstances, the Hatch-Waxman Act is intended to provide each of these "first-filers" with equal rights and opportunities to market their generic version of the drug.

For that reason, it is appropriate that the actions against all defendants proceed in the same district to provide a level playing field for each generic manufacturer in their bid to manufacture a generic version of sanofi-aventis's Uroxatral® brand drug product. Allowing a second-filed action related to just one ANDA to proceed in a different district would run counter to the purpose of the Hatch-Waxman Act, and could potentially prejudice the rights of the other defendants, particularly in circumstances where they cannot participate in the parallel actions.

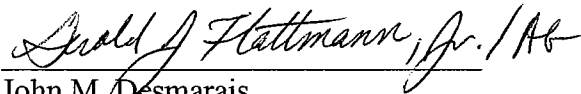
Thus, the policy of the Hatch-Waxman Act also favors consolidation of all four actions in the District of Delaware where the first-filed actions are already pending against all defendants.

V. CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Panel transfer *Sanofi-aventis et al. v. Apotex Inc. et al.*, No. 07-61800-CIV-MORENO/SIMONTON, pending in the Southern District of Florida to the District of Delaware, and consolidate that action for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407 with the parallel first-filed action, *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), and two related actions, *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Labs, Inc.*, No. 07-574 (GMS) (MPT), pending in that District.

Dated: February 1, 2008.

Respectfully submitted,



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EXHIBIT R

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE
DEFENSES AND COUNTERCLAIMS**

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively “Sanofi”) as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufactures numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used “throughout the United States”, and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs’ Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) and that a copy of the ‘491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court’s personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through

any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

ANSWER: For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. By virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Apotex, Inc. and Apotex Corp. admit that venue is proper in this judicial district.

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

ANSWER: Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

Acts Giving Rise to this Action
Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory

requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007 Civil action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

GENERAL DENIAL

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following affirmative defenses to the Complaint:

FIRST AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted. Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

COUNTERCLAIMS

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:

The Parties

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.
2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.
3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

Jurisdiction and Venue

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter “Hatch-Waxman Amendments”), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter “MMA”).
6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).
7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District

and because Apotex Corp. conducts substantial business in and has regular systematic contacts with this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

Patents-in-Suit

9. On or about April 28, 1987, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 4,661,491 (“the ’491 patent”), entitled “AFLUZOSINE COMPOSITIONS AND USE” to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the ’491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 (“the ’940 patent”) entitled “TABLET WITH CONTROLLED RELEASE OF AFLUZOSINE CHLORHYDRATE” to Laurretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in ’940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the ’940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The ’491 patent and the ’940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the ’940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 70-013 to the FDA. Apotex Inc.’s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.

16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the new drug for which ANDA 70-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the '940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being

injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '491 Patent)

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

COUNT II
(Declaration of Invalidity of the '491 Patent)

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

COUNT III
(Declaration of Non-infringement of the '940 Patent)

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

COUNT IV
(Declaration of Invalidity of the '940 Patent)

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.

33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

- (a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;
- (b) Declaring that the claims of the '491 patent are invalid;
- (c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;
- (d) Declaring that the claims of the '940 patent are invalid;
- (e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and
- (f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

DATED: December 28, 2007
Miami, FL

Respectfully submitted,

s/. Stephen J. Bronis

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Attorneys for Apotex Corp. and Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on December 28, 2007 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

SERVICE LIST

Case No. 07-61800-CIV-MORENO/SIMONTON

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EXHIBIT S

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

**ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE
DEFENSES AND AMENDED COUNTERCLAIMS¹**

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively “Sanofi”) as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

¹ This pleading is identical to the pleading filed December 28, 2007, except that certain inadvertent typographical errors in paragraphs 9, 11, 15 and 16 of the Counterclaims have been corrected.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufactures numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used “throughout the United States”, and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs’ Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) and that a copy of the ‘491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court’s personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent

infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

ANSWER: For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. By virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Apotex, Inc. and Apotex Corp. admit that venue is proper in this judicial district.

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

ANSWER: Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral[®] and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

Acts Giving Rise to this Action
Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral[®] brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory

requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007 Civil action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

GENERAL DENIAL

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following affirmative defenses to the Complaint:

FIRST AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted. Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

AMENDED COUNTERCLAIMS

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:

The Parties

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.
2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.
3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

Jurisdiction and Venue

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter “Hatch-Waxman Amendments”), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter “MMA”).
6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).
7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District

and because Apotex Corp. conducts substantial business in and has regular systematic contacts with this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

Patents-in-Suit

9. On or about April 28, 1987, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 4,661,491 (“the ’491 patent”), entitled “ALFUZOSINE COMPOSITIONS AND USE” to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the ’491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 (“the ’940 patent”) entitled “TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE” to Laretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in ’940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the ’940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The ’491 patent and the ’940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the ’940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 79-013 to the FDA. Apotex Inc.’s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.

16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the new drug for which ANDA 79-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the '940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being

injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '491 Patent)

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

COUNT II
(Declaration of Invalidity of the '491 Patent)

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

COUNT III
(Declaration of Non-infringement of the '940 Patent)

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

COUNT IV
(Declaration of Invalidity of the '940 Patent)

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.

33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

- (a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;
- (b) Declaring that the claims of the '491 patent are invalid;
- (c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;
- (d) Declaring that the claims of the '940 patent are invalid;
- (e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and
- (f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

DATED: January 2, 2008
Miami, FL

Respectfully submitted,

s/. Stephen J. Bronis

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s/. Robert B. Breisblatt

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Attorneys for Apotex Corp. and Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on January 2, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

SERVICE LIST

Case No. 07-61800-CIV-MORENO/SIMONTON

Alfred John Saikali
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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

VS.

APOTEX INC. and
APOTEX CORP.,

Defendants.

Case No. 07 C 61800

Judge Moreno

Magistrate Judge Simonton

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S RULE 26(a) (1)
INITIAL DISCLOSURES**

Pursuant to Fed. R. Civ. P. 26(a) (1), Defendants Apotex Inc. and Apotex Corp. (collectively “Apotex”) make the following initial disclosures based on the information available to Defendants at this time. Defendants reserve the right to supplement these disclosures.

A. The Name and, If Known, the Address and Telephone Number of Each Individual Likely to Have Discoverable Information that the Disclosing Party May Use to Support Its Claims or Defenses, Unless Solely for Impeachment, Identifying the Subjects of the Information

1. Francois Regnier
6, rue de la Source
54000 Nancy, France

Subjects: The subject matter claimed in U.S. Patent No. 4,661,491; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

2. Helmuth A. Wegner
Wegner & Bretschneider
PO Box 18218
Washington, DC 20036-8218
(202) 887-0400

Subjects: The preparation of the application and prosecution of the application for U.S. Patent No. 4,661,491; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

3. Laretta Maggi
Via Folperti N.3
I-27100 Pavia
Italy

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

4. Ubaldo Conte
Via Treviglio n.6
I-20052 Busto Arisizio
Italy

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

5. Pascal Grenier
23a rue du Marechal de Saxe
68300 Saint Louis
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

6. Guy Vergnault
9 rue du Bois Vert
68300 Saint Louis
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

7. Alain Dufour
42 Avenue de Saxe
75007 Paris
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

8. Francois Xavier Jarreau
5 rue L. Herve
78000 Versailles
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

9. Clemence Rauch-Desanti
19 rue Prix d'Amerique
77330 Ozoire la Ferriere
France

Subjects: The subject matter claimed in U.S. Patent No. 6,149,940; the preparation of the applications and the prosecution of the applications for the above-identified patent, the development of any products that Sanofi-Aventis or Sanofi-Aventis U.S. L.L.C. contend are covered by the claims of the above-identified patent; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

10. D. Douglas Price
Jacobson, Price, Holman 7 Stern, PLLC
400 7th Street, N.W., Suite 600
Washington, DC 20004
(202) 638-6666

Subjects: The preparation of the application and prosecution of the application for U.S. Patent No. 6,149,940; information regarding Apotex's counterclaims and defenses of non-infringement and/or invalidity.

11. Bernice Tao
Apotex Inc.
c/o Welsh & Katz, Ltd.
120 S. Riverside Plaza, 22nd Floor
Chicago, IL 60606

Subjects: Information on the non-infringement of the patents at issue.

12. Any other person substantively involved in the preparation and/or prosecution of U.S. Patent Nos. 4,661,491 and 6,149,940.

B. A Copy of, or a Description by Category and Location of, All Documents, Data Compilations, and Tangible Things that Are in Possession, Custody, or Control of the Party and that the Disclosing Party May Use to Support Its Claims or Defenses, Unless Solely for Impeachment

Defendants identify the following documents, compilations and things that

Defendants may use to support their claims or defenses:

1. Prior art and other documents and things identified in Apotex Inc's August 14, 2007 and October 15, 2007 Paragraph IV letters.

2. Documents related to U.S. Patents No. 4,661,491 and 6,149,940, including the patents themselves, the prosecution histories, and the prior art cited during the prosecution of the patents.

3. Abbreviated New Drug Application No. 79-013.

C. A Computation of Any Category of Damages Claimed by the Disclosing Party, Making Available for Inspection and Copying as Under Rule 34 and Documents or Other Evidentiary Material, Not Privileged or Protected from Disclosure, in Which Such Computation Is Based, Including Materials Bearing on the Nature and Extent of Injuries Suffered.

Defendants are not seeking damages at this time.

D. For Inspection and Copying as Under Rule 34 Any Insurance Agreement Under Which Any Person Carrying on an Insurance Business May Be Liable to Satisfy Part or All of a Judgment Which May Be Entered in the Action or to Indemnify or Reimburse for Payments Made to Satisfy Judgment

Defendants have not identified any documents of this type at this time.

Dated: January 17, 2008



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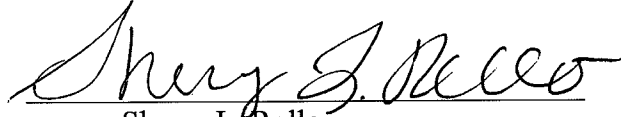
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic and U.S. mail to the following:

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January 17, 2008


Sherry L. Rollo

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January 17, 2008

**By Federal Express and
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Re: *Sanofi-aventis et al. v. Apotex Inc. et al.*,
Case No. 07-61800-CIV-MORENO/SIMONTON

Dear Steven and Stephen:

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") hereby provide the following disclosures required by the Court's Pretrial Order Setting Conference dated January 3, 2008 Pursuant to the Local Rules 16.1.B.1 & 16.1.B.2 of the Southern District of Florida, Miami Division to Defendants Apotex Inc. and Apotex Corp. (collectively "Defendants").¹ These disclosures are based upon information reasonably and presently available to sanofi-aventis, without the benefit of formal discovery, production of documents, or any meaningful disclosures from the Defendants. Accordingly, sanofi-aventis reserves the right to amend and/or supplement these disclosures in its formal Initial Disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1), that are currently due on January 31, 2008, or any supplements or amendments to those disclosures as its investigation and discovery proceeds in this action.

¹ The parties held a conference call on January 15, 2008 pursuant to the Court's January 3, 2008 Pretrial Order Setting Conference and discussed issues related to some aspects of that Order and sanofi-aventis's request for a meet and confer regarding moving the case to the Complex Track from the Expedited Track.

KIRKLAND & ELLIS LLP

Steven E. Feldman, Esq.
 Stephen J. Bronis, Esq.
 January 17, 2008
 Page 2

Sanofi-aventis expects that the parties will continue to meet and confer with respect to these issues as well as the parties' other obligations under Federal Rule of Civil Procedure 26(f) while jointly preparing the Joint Conference Report pursuant to S.D. Fla. L.R. 16.1.B.2 that is currently due on January 31, 2008.

Disclosures

(1) Documents (S.D. Fla. L.R. 16.1.B.1 and 2) - The parties shall determine the procedure for exchanging a copy of or a description by category and location of all documents and other evidence that is reasonably available and that a party expects to offer or may offer if the need arises. Fed. R. Civ. P. 26(a)(1)(B).

Response: Sanofi-aventis lists the following categories of documents and the location of such documents that it expects to offer or may offer if the need arises in this litigation based on its investigation to date. The parties are continuing to meet and confer concerning the form of and procedure for document production in this action. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Location	Description
sanofi-aventis 174 avenue de France 75635 Paris cedex 13	Certain documents concerning the marketing and sales of Uroxatral®, licensing administration related to Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.
sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807	Certain documents concerning the marketing and sales of Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.
sanofi-aventis 46 quai de la Rapée 75012 Paris	Certain documents concerning the marketing of Uroxatral®.
sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex	Certain documents concerning the conception and reduction to practice of the inventions claimed in United States Patent Nos. 4,661,491 and 6,149,940, design and development of Uroxatral®, clinical trials related to

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Location	Description
	Uroxatral®, and regulatory activities related to Uroxatral®.
sanofi-aventis Research & Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04	Certain documents concerning pharmacokinetic studies related to Uroxatral®.
sanofi-aventis Research & Development 2-8 rue de Rouen Zone industrielle de Limay 78440 Porcheville	Certain documents concerning animal studies related to Uroxatral®.
Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2	Certain documents concerning the industrial design and manufacture of Uroxatral®.
sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355	Certain documents concerning the industrial design of, manufacture of, and regulatory filings for Uroxatral®.
sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, NJ 08807-0912	Certain documents concerning the marketing of Uroxatral®.

(1)(a) Documents include computations of the nature and extent of any category of damages claimed by the disclosing party unless the computations are privileged or otherwise protected from disclosure. Fed. R. Civ. P. 26(a)(1)(C).

Response: Under 35 U.S.C. § 271(e)(4)(C), damages are not available with respect to the patent claims in this action unless Defendants violate applicable laws and regulations and engage in any commercial manufacture, use, importation, offer to sell or sale of the generic product described in ANDA 79-013 within the United States. To sanofi-aventis's knowledge, Defendants have not engaged in any such commercial activity and, as a result, damages are not available with respect to the patent claims in this action at this time. Accordingly, sanofi-aventis is unable to calculate any damages at this time.

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(1)(b) Documents include insurance agreements which may be at issue with the satisfaction of the judgment. Fed. R. Civ. P. 26(a)(1)(D).

Response: Sanofi-aventis is not presently aware of any documents that relate to section 1(b).

(2) **List of Witnesses** - The parties shall exchange the name, address and telephone number of each individual known to have knowledge of the facts supporting the material allegations of the pleading filed by the party. Fed. R. Civ. P. 26(a)(1)(A). The parties have a continuing obligation to disclose this information.

Response: Sanofi-aventis identifies the following individuals known to have knowledge of the facts supporting the material allegations of the pleadings filed by sanofi-aventis, based on its investigation to date. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Individual and Contact Information	Subject of Information Known
Alaux, Gerard sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Andre, Frederic sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.

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Steven E. Feldman, Esq.
 Stephen J. Bronis, Esq.
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Individual and Contact Information	Subject of Information Known
Barry, Meredith sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Barry, Patrick sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Boisson, Gilles sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00 Contact through sanofi-aventis's counsel of record.	Knowledge of certain license administration activities related to Uroxatral®.
Borneman, James sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.

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Steven E. Feldman, Esq.

Stephen J. Bronis, Esq.

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Individual and Contact Information	Subject of Information Known
Bretschneider, Barry E. Morrison & Foerster LLP, 1650 Tysons Boulevard Suite 400 McLean, VA 22102 Tel.: +1 202 887 1500	Knowledge of the prosecution of United States Patent No. 4,661,491.
Brohier, Sylvie sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge of certain clinical trials related to Uroxatral®.
Burg, Christine sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00 Contact through sanofi-aventis's counsel of record.	Knowledge of certain license administration activities related to Uroxatral®.
Conte, Ubaldo Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.

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Stephen J. Bronis, Esq.

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Individual and Contact Information	Subject of Information Known
<p>Depaire, Olivier Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2 France Tel.: +33 (0)2 47 42 35 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain industrial development activities related to Uroxatral®.</p>
<p>DeSieno, Mark sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355 Tel.: +1 610 889 8600</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain industrial development activities related to Uroxatral®.</p>
<p>Dufour, Alain Boulogne-Billancourt, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Egan, Beth sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, NJ 08807-0912 United States Tel.: +1 908 243 6000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>

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Individual and Contact Information	Subject of Information Known
<p>Gardella, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain life cycle management activities related to Uroxatral®.</p>
<p>Gaydos, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain regulatory and marketing activities related to Uroxatral®.</p>
<p>Grenier, Pascal Address unknown</p> <p>Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll & Rooney PC.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Jacobson Jr., Harvey Jacobson Holman PLLC 400 Seventh St., NW Washington, DC 20004 Tel.: +1 202 638 6666</p>	<p>Knowledge of the prosecution of United States Patent No. 6,149,940.</p>
<p>Jarreau, Francois Xavier Paris, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>

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Individual and Contact Information	Subject of Information Known
<p>Kugel, Dominique sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain prosecution activities related to United States Patent No. 6,149,940.</p>
<p>Legathe, Agnes sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain regulatory activities related to Uroxatral®.</p>
<p>Lewis, Gareth sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain development activities related to Uroxatral®.</p>
<p>Maggi, Laretta Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>

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Individual and Contact Information	Subject of Information Known
Marcelli, Mihaela sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00 Contact through sanofi-aventis's counsel of record.	Knowledge of certain license administration activities related to Uroxatral®.
Ogle, Mary sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Papp, Diane sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Penfornis, M.D. Catherine sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge of certain regulatory activities related to Uroxatral®.

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Individual and Contact Information	Subject of Information Known
Rauch-Desanti, Clemence sanofi-aventis Research & Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04 France Tel.: +33 (0)4 67 10 67 10 Contact through sanofi-aventis's counsel of record.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Regnier, Francois, M.D. Nancy, France Contact through sanofi-aventis's counsel of record.	Knowledge of the subject matter of United States Patent No. 4,661,491, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Sant, M.D., Granham sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities and medical affairs related to Uroxatral®.
Sieuw, Pascal sanofi-aventis 46 quai de la Rapée 75601 Paris cedex 12 France Tel.: +33 (0)1 55 71 30 07 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Thouret-Lemaitre, Elizabeth Paris, France Contact through sanofi-aventis's counsel of record.	Knowledge of certain prosecution activities related to United States Patent Nos. 4,661,491 and 6,149,940.

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Individual and Contact Information	Subject of Information Known
<p>Tina, Jay sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral® and BPH registry.</p>
<p>Trussardi, Claire sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral®.</p>
<p>Vergnault, Guy Address unknown</p> <p>Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll & Rooney PC.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Wegner, Harold C. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007 Tel.: +1 202 672 5300</p>	<p>Knowledge of the prosecution of United States Patent No. 4,661,491.</p>
<p>Wegner, Helmuth A. address unknown</p>	<p>Knowledge of the prosecution of United States Patent No. 4,661,491.</p>


(3) **Settlement Discussions (S.D. Fla. L.R. 16.1.B.2)**- The parties shall discuss the nature and basis of their claims and defenses and the possibilities for a prompt settlement or resolution of the case.

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Response: On January 15, 2008, the parties discussed the potential for settlement with respect to this action and concluded that a settlement was unlikely now or at any date in the near future.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. T. Vuk', with a long horizontal line extending to the right.

William T. Vuk

cc (via email only):
Jack Blumenfeld, Esq.
Jennifer Coberly, Esq.
Richard L. Horwitz, Esq.
Edward A. Moss, Esq.
Alfred J. Saikali, Esq.

EXHIBIT V

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION**

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

_____ /

PLAINTIFFS' INITIAL DISCLOSURES PURSUANT TO RULE 26(A)(1)

Pursuant to Federal Rules of Civil Procedure 26(a)(1), Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis"), based upon information reasonably available to sanofi-aventis at this time, hereby provides its initial disclosures to Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex").

These disclosures are in furtherance of sanofi-aventis's disclosures pursuant to the Court's Pretrial Order Setting Conference dated January 3, 2008 Pursuant to the Local Rules 16.1.B.1 & 16.1.B.2 of the Southern District of Florida, Miami Division and are based upon information reasonably and presently available to sanofi-aventis, without the benefit of formal discovery, production of documents, or any meaningful disclosures from the Defendants. Accordingly, sanofi-aventis reserves the right to amend and/or supplement these disclosures as its investigation and discovery proceeds in this action.

Initial Disclosures

Rule 26.(a)(1)(A)(i) the name and, if known, the address and telephone number of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment.

Response: Sanofi-aventis identifies the following individuals likely to have discoverable information and whom sanofi-aventis may use to support its claims or defenses, based on its investigation to date. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Individual and Contact Information	Subject of Information Known
Alaux, Gerard sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Alexander, Michael D. sanofi-aventis U.S. LLC Route #202-206/P.O. Box 6800 Bridgewater, New Jersey 08807-0800 Tel.: +1 610 889 8458 Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain activities related to the '491 patent.
Andersson, K. E. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Andre, Frederic sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.

Individual and Contact Information	Subject of Information Known
<p>Barry, Meredith sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Barry, Patrick sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Boisson, Gilles sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Borneman, James sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Bretschneider, Barry E. Morrison & Foerster LLP, 1650 Tysons Boulevard Suite 400 McLean, Virginia 22102 Tel.: +1 202 887 1500</p>	<p>Knowledge of the prosecution of United States Patent No. 4,661,491.</p>
<p>Brohier, Sylvie sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex France Tel: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral®.</p>

Individual and Contact Information	Subject of Information Known
<p>Burg, Christine sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Icilio Cavero, Ph. D. Lucca, Italy</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Ceccardi, R. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Conte, Ubaldo Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Depaire, Olivier Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2 France Tel.: +33 (0)2 47 42 35 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain industrial development activities related to Uroxatral®.</p>
<p>DeSieno, Mark sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355 Tel.: +1 610 889 8600</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain industrial development activities related to Uroxatral®.</p>
<p>Darkes, Paul R. sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, Pennsylvania 19355 Tel.: +1 610 889 8600</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain activities related to the '491 patent.</p>

Individual and Contact Information	Subject of Information Known
Doyle, P.T. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Dufour, Alain Boulogne-Billancourt, France Contact through sanofi-aventis's counsel of record.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Egan, Beth sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, New Jersey 08807-0912 Tel.: +1 908 243 6000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain marketing activities related to Uroxatral®.
Ek, A. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Galzin, Anne-Marie address unknown Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Gardella, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain life cycle management activities related to Uroxatral®.
Gaydos, Mark sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000 Contact through sanofi-aventis's counsel of record.	Knowledge of certain regulatory and marketing activities related to Uroxatral®.
Grenier, Pascal Muttentz, Switzerland Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll & Rooney PC.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.

Individual and Contact Information	Subject of Information Known
Hedlund, H. address unknown	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Jacobson Jr., Harvey Jacobson Holman PLLC 400 Seventh St., NW Washington, DC 20004 Tel.: +1 202 638 6666	Knowledge of the prosecution of United States Patent No. 6,149,940.
Jarreau, Francois Xavier Versailles, France Contact through sanofi-aventis's counsel of record.	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.
Kugel, Dominique sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00 Contact through sanofi-aventis's counsel of record.	Knowledge of certain prosecution activities related to United States Patent No. 6,149,940.
Langer, Salomon Z. Tel Aviv, Israel Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.
Legathe, Agnes sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge of certain regulatory activities related to Uroxatral®.
Lewis, Gareth sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77 Contact through sanofi-aventis's counsel of record.	Knowledge concerning certain development activities related to Uroxatral®.
Maggi, Lauretta Università degli Studi di Pavia Strada Nuova, 65 - 27100 Pavia Italy Tel.: +39.0382.9811	Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.

Individual and Contact Information	Subject of Information Known
<p>Manoury, Phillipe, Ph.D. Sceaux, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Marcelli, Mihaela sanofi-aventis 174 avenue de France 75635 Paris cedex 13 France Tel.: +33 (0)1 53 77 40 00</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain license administration activities related to Uroxatral®.</p>
<p>Margonato, A. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Mayo, M. E. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Oehler, Ross J. Collegeville, Pennsylvania</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge concerning certain activities related to the '491 patent.</p>
<p>Ogle, Mary sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Papp, Diane sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Penfornis, M.D. Catherine sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain regulatory activities related to Uroxatral®.</p>

Individual and Contact Information	Subject of Information Known
<p>Pimoule, Carmen address unknown</p> <p>Contact through sanofi-aventis's counsel of record</p>	<p>Knowledge of the information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Poopalasingham, N. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Price, D. Douglas 1134 Randolph Road McLean, Virginia 22101 Tel.: +1 703 442 3364</p>	<p>Knowledge of the prosecution of United States Patent No. 6,149,940.</p>
<p>Rauch, Clemence sanofi-aventis Research & Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04 France Tel.: +33 (0)4 67 10 67 10</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Regnier, Francois, M.D. Nancy, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of the subject matter of United States Patent No. 4,661,491, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Rigatti, P. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Ronchi, F. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Rossini, B. M. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>
<p>Sant, M.D., Granham sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities and medical affairs related to Uroxatral®.</p>

Individual and Contact Information	Subject of Information Known
<p>Sieuw, Pascal sanofi-aventis 46 quai de la Rapée 75601 Paris cedex 12 France Tel.: +33 (0)1 55 71 30 07</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain marketing activities related to Uroxatral®.</p>
<p>Tao, Bernice Director, Regulatory Affairs US Apotex Inc. 150 Signet Drive Toronto, Ontario M9L 1T9</p>	<p>Knowledge of certain activities related to the preparation and filing of ANDA 79-013 and the infringement of the patents at issue.</p>
<p>Thouret-Lemaitre, Elizabeth Paris, France</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain prosecution activities related to United States Patent Nos. 4,661,491 and 6,149,940.</p>
<p>Tina, Jay sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807 Tel.: +1 908 981 5000</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral® and BPH registry.</p>
<p>Trussardi, Claire sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex, France Tel.: +33 (0)1 69 79 77 77</p> <p>Contact through sanofi-aventis's counsel of record.</p>	<p>Knowledge of certain clinical trials related to Uroxatral®.</p>
<p>Vergnault, Guy Muttentz, Switzerland</p> <p>Contact through Constance S. Huttner or Ryan P. Farley at Buchanan Ingersoll & Rooney PC.</p>	<p>Knowledge of the subject matter of United States Patent No. 6,149,940, the conception and reduction to practice of the inventions claimed in the patent, and the prosecution of the patent.</p>
<p>Wegner, Harold C. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007 Tel.: +1 202 672 5300</p>	<p>Knowledge of the prosecution of United States Patent No. 4,661,491.</p>
<p>Whitfield, H. N. address unknown</p>	<p>Knowledge concerning certain information contained within or related to art cited in Apotex's Paragraph IV Certification notice letter dated October 25, 2007 for ANDA 79-013.</p>

Individual and Contact Information	Subject of Information Known
Authors of the prior art references cited within the Paragraph IV Certification notice letters regarding ANDAs related to alfuzosin hydrochloride 10 mg extended release tablets received by sanofi-aventis from Actavis South Atlantic LLC, Aurobindo Pharma Ltd., Barr Laboratories, Inc., Mylan Pharmaceuticals Inc., Ranbaxy Laboratories Limited, Sun Pharmaceutical Industries, Inc., Teva Pharmaceuticals USA, Inc., and Torrent Pharmaceuticals Limited.	Knowledge concerning certain information contained within or related to art cited in the Paragraph IV Certification notice letters sent to sanofi-aventis regarding ANDAs related to alfuzosin hydrochloride 10 mg extended release tablets.

Upon information and belief, certain past and/or present employees and agents of Defendants having substantial involvement in the decision to file, the preparation and submission of Abbreviated New Drug Application 79-013; and the research, development and formulation pertaining to the proposed generic product defined by ANDA 79-013.

Rule 26.(a)(1)(A)(ii): a copy—or a description by category and location—of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses, unless the use would be solely for impeachment.

Response: Sanofi-aventis lists the following categories and locations of documents, electronically stored information and tangible things that sanofi-aventis has in its possession, custody, or control and may use to support its claims of defenses in this litigation based on its investigation to date. The parties are continuing to meet and confer concerning the form of and procedure for document production in this action. Sanofi-aventis reserves the right to supplement and/or amend this list as its investigation and discovery proceeds in this action.

Location	Description
sanofi-aventis 174 avenue de France 75635 Paris cedex 13	Certain documents concerning the marketing and sales of Uroxatral®, licensing administration related to Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.
sanofi-aventis U.S. LLC 55 Corporate Drive Bridgewater, New Jersey 00807	Certain documents concerning the marketing and sales of Uroxatral®, United States Patent Nos. 4,661,491 and 6,149,940 and their prosecutions, and other business records.

Location	Description
sanofi-aventis 46 quai de la Rapée 75012 Paris	Certain documents concerning the marketing of Uroxatral®.
sanofi-aventis Research & Development 1 avenue Pierre Brossolette 91385 Chilly-Mazarin cedex	Certain documents concerning the conception and reduction to practice of the inventions claimed in United States Patent Nos. 4,661,491 and 6,149,940, design and development of Uroxatral®, clinical trials related to Uroxatral®, and regulatory activities related to Uroxatral®.
sanofi-aventis Research & Development 371 rue du Pr Joseph Blayac 34184 Montpellier cedex 04	Certain documents concerning pharmacokinetic studies related to Uroxatral®.
sanofi-aventis Research & Development 2-8 rue de Rouen Zone industrielle de Limay 78440 Porcheville	Certain documents concerning animal studies related to Uroxatral®.
Sanofi Winthrop Industrie 30-36 avenue Gustave Eiffel BP 27166 37071 Tours cedex 2	Certain documents concerning the industrial design and manufacture of Uroxatral®.
sanofi-aventis U.S. LLC 9 Great Valley Parkway Malvern, PA 19355	Certain documents concerning the industrial design of, manufacture of, and regulatory filings for Uroxatral®.
sanofi-aventis U.S. LLC 300-400 Somerset Corporate Boulevard Bridgewater, NJ 08807-0912	Certain documents concerning the marketing of Uroxatral®.

Upon information and belief, Jagotec AG and SkyePharma PLC may also be in possession of documents, electronically stored information and tangible things potentially relevant to Apotex's counterclaims and, to the extent that the Court has jurisdiction over those counterclaims, sanofi-aventis's defenses to those counterclaims, including United States Patent No. 6,149,940 and its prosecution, development and use of the Geomatrix® technology, and agreements between Jagotec and/or SkyePharma and sanofi-aventis or its predecessors:

JAGOTEC AG
Seestrasse 91
CH-6052 Hergiswil, Switzerland

JAGOTEC AG
Eptingerstrasse 51
MuttENZ 4132
Switzerland

SkyePharma PLC
105 Piccadilly
W1J 7NJ
Great Britain

Rule 26.(a)(1)(A)(iii) a computation of each category of damages claimed by the disclosing party—who must also make available for inspection and copying as under Rule 34 the documents or other evidentiary material, unless privileged or protected from disclosure, on which each computation is based, including materials bearing on the nature and extent of injuries suffered.

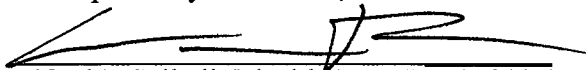
Response: Under 35 U.S.C. § 271(e)(4)(C), damages are not available with respect to the patent claims in this action unless Defendants violate applicable laws and regulations and engage in any commercial manufacture, use, importation, offer to sell or sale of the generic product described in ANDA 79-013 within the United States. To sanofi-aventis's knowledge, Defendants have not engaged in any such commercial activity and, as a result, damages are not available with respect to the patent claims in this action at this time. Accordingly, sanofi-aventis is unable to calculate any damages at this time.

Rule 26.(a)(1)(A)(iv) for inspection and copying as under Rule 34, any insurance agreement under which an insurance business may be liable to satisfy all or part of a possible judgment in the action or to indemnify or reimburse for payments made to satisfy the judgment.

Response: Sanofi-aventis states that it is not aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments made to satisfy any such judgment.

Dated: January 31, 2008

Respectfully submitted,



Alfred J. Saikali (Florida Bar No.: 178195)

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153 E. 53rd Street

New York, NY 10022-4611

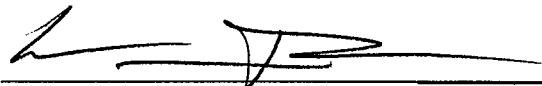
Tel: (212) 446-4800

Fax: (212) 446-4900

*Attorneys for Plaintiffs sanofi-aventis and
sanofi-aventis U.S. LLC*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by U.S. Mail and by electronic mail on January 31, 2008, on all counsel or parties of record on the attached service list.



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*Attorneys for Plaintiffs sanofi-aventis and
sanofi-aventis U.S. LLC*

SERVICE LIST

SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL

Case No.: 07-61800-CIV-Moreno/Simonton

**United States District Court
Southern District of Florida
(Miami Division)**

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ZUCKERMAN SPAEDER, LLP
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Chicago, IL 60606-3912

EXHIBIT W

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

SANOFI-AVENTIS and)	
SANOFI-AVENTIS U.S. LLC,)	
)	Case No. 07 C 61800
Plaintiffs,)	Judge Moreno
)	
)	
vs.)	Magistrate Judge Simonton
)	
APOTEX INC. and)	
APOTEX CORP.,)	
)	
Defendants.)	

**DEFENDANTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND
THINGS TO PLAINTIFF**

Pursuant to Federal Rules of Civil Procedure 26 and 34, Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Defendant"), through counsel, hereby request that Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. L.L.C. (collectively "Sanofi" or "Plaintiff"), answer in writing and produce documents and things for inspection and copying at the offices of Welsh & Katz, LTD, 120 S. Riverside Plaza, Chicago, Illinois 60606, within thirty (30) days of the date of service of this request.

A Protective Order has not yet been entered in this case. Apotex agrees to treat all documents produced as Attorneys Eyes Only until a Protective Order is entered by the Court.

DEFINITIONS AND INSTRUCTIONS

A. **Parties.** The terms "plaintiff" and "defendants" as well as a party's full or abbreviated name or a pronoun referring to a party mean the party and, where applicable, its officers, directors, employees, partners, corporate parent, subsidiaries,

affiliates, or predecessors in interest. This definition is not intended to impose a discovery obligation on any person who is not a party to the litigation unless that person is obligated to co-operate with Sanofi with regard to the instant action.

B. **Communication.** The term “communication” means the transmittal of information in the form of facts, ideas, inquiries, or otherwise.

C. **Concern(s), Concerning, Concerned with, Relate(s) or Relating to.** The terms “concern(s),” “concerning,” “concerned with,” “relates,” or “relating to” are used interchangeably and mean concerning, evidencing, pertaining to, referring to, mentioning, memorializing, commenting on, containing, identifying, connected with, contemplating, discussing, stating, describing, reflecting, dealing with, consisting of, constituting, comprising, recording, or being relevant to all or any portion of the specified fact, conditions, events or incidents.

D. **Date.** The term “Date” means the exact day, month and year, if known or ascertainable, or, if not, the best approximation possible (including the temporal relationship to other events).

E. **Document.** The term “document” shall mean every means of recording any form of communication or representation upon any tangible thing, including letters, numbers, words, pictures, sounds, or symbols, or combinations thereof, whether recorded by handwriting, printing, photostatic, or photographic means, electronically stored information, including information stored on magnetic impulse, tape, computer disk, CD-ROM or any other form of data storage, data compilation, or mechanical or electronic recording, and all other tangible things which come within the meaning of writing contained in Rule 1001 of the Federal Rules of Evidence, or within the meaning of

"document" or "tangible thing" contained in Rule 34 of the Federal Rules of Civil Procedure.

F. **Person.** The term "person" is defined as any natural person or any business, legal or governmental entity or association, and any functional division thereof.

G. **Alfuzosin.** The term "Alfuzosin" or "Alfuzosine" is defined as the drug compound of this name identified in the '940 or '991 patents, including any compound of the formula N-[3-[(4-amino-6,7-dimethoxy-quinazolin-2-yl)-methyl-amino]propyl] tetrahydrofuran-2-carboxamide and any salts thereof.

H. The following **rules of construction** apply to these discovery requests, definitions, and instructions:

- i. **All/Each/Any.** The terms "all," "each," and "any" shall be construed as inclusive and synonymous and are as inclusive in scope as permitted by the Federal Rules of Civil Procedure.
- ii. **And/Or.** The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside the scope.
- iii. **Number.** The use of the singular form of any word includes the plural and vice versa.
- iv. **Independence.** Except as otherwise expressly directed herein, each paragraph and subparagraph of an interrogatory and/or document request shall be construed independently and not by reference to any other paragraph or subparagraph herein for the purpose of limiting the scope of the interrogatory and/or document request being responded to.

I. Each request to produce documents shall be construed to request documents within your possession, custody, or control. Separately for each Request, if any document responsive to that Request once was in your possession, custody, or

control but has been lost, discarded, destroyed, or is otherwise presently not within your possession, custody, or control:

- i. identify the unavailable document;
- ii. identify any and all persons who lost, discarded, or destroyed the document or caused the document to become otherwise unavailable;
- iii. identify any and all persons likely to have knowledge concerning the circumstances by which the document was lost, discarded, destroyed, or otherwise became unavailable;
- iv. identify any and all persons likely to have knowledge concerning the contents of the document that was lost, discarded, or otherwise became unavailable.

J. When producing documents, Plaintiff should produce the documents as they are kept in the ordinary course of business or organize and label them to correspond with the numbered categories in this Request.

K. If Plaintiff finds the meaning of any terms in these requests unclear, Plaintiff shall assume a reasonable meaning, state what the assumed meaning is, and respond to the request according to the assumed meaning.

L. If Plaintiff objects to any request or part of any request, the reason(s) for the objection shall be stated in full. If an objection is made to any request, production should be made of all documents or things to which the objection does not relate.

M. If any information, document or thing responsive to any of the following production requests is withheld on the basis of privilege and/or work-product doctrine, the following information is requested with respect to any such refusal:

- i. the privilege and/or work-product rule of law being relied upon;
- ii. the date the document was created;

- iii. the identity of the person or persons who created the information, document, or thing;
- iv. the identity of the present custodian of the information, document, or thing;
- v. the addressee(s) and all other recipients of the information, document, or thing;
- vi. the subject matter of the information, document or thing; and
- vii. the location of the information, document or thing.

N. **The '940 Patent.** The term "the '940 Patent" means U.S. Patent No. 6,149,940.

O. **The '491 Patent.** The term "the '491 Patent" means U.S. Patent No. 4,661,491.

P. **Patents at Issue.** The term "patents at issue" means U.S. Patent No. 6,149,940 and U.S. Patent No. 4,661,491.

These requests for production of documents and things are continuing in nature pursuant to Rule 26(e), Fed. R. Civ. P., and require timely supplementation of documents and information as they come within Sanofi's possession custody and control.

REQUESTS

1. All documents concerning any proposal, consideration or decision by Plaintiff to draft and/or file the patents at issue.
2. All documents reviewed and/or relied on by Plaintiff in making the determination to seek patent protection for the subject matter of the patents at issue
3. All documents which are relevant to establishing a date of invention by Plaintiff, or any person associated with Plaintiff, earlier than the filing date for each of the patents at issue.
4. All documents and communications that refer or relate to the preparation and/or prosecution of the patents at issue and/or any U.S. applications or foreign applications that constitute or are based in whole or in part on, or which claim priority from, or are the basis of priority for, any of the applications in the family of patent applications leading to the patents at issue and any related oppositions, re-examinations, and/or reissue proceedings including, without limitation:
 - a. all documents that provided the bases for any of said applications or proceedings;
 - b. all files in Plaintiff's possession, custody or control regarding the patents at issue, the patent applications for the patents at issue, or any related U.S. or foreign patents or applications;
 - c. all disclosures of the subject matter of any of said applications or proceedings;
 - d. all communications between the alleged inventor and his patent attorney(s) or agent(s) concerning the subject matter described or claimed in any of said applications or proceedings;
 - e. all documents referring or relating to any information used or supplied by the alleged inventor in connection with the preparation or prosecution of any of said applications or proceedings including invention disclosures prepared by or for the inventor;

- f. all drafts of any said applications or proceedings;
- g. all patents, publications, references or prior art, and all records or documents referring or relating to any prior art or possible prior art, and all records or documents referring or relating to any prior art or any possible ground of unpatentability and/or invalidity, submitted, cited, discussed or considered in connection with any of said applications or proceedings;
- h. all documents referring or relating to the citation of, decision not to cite, or failure to cite, any references and/or prior art to the PTO or other patent office or patent authority in connection with said applications or proceedings; and
- i. all copies (including drafts) of responses to Office Actions, amendments, affidavits, declarations and other communications or submissions of any kind with or to the PTO or other patent office, or patent authority with respect to any of said applications or proceedings.

5. All documents and communications concerning any search, investigation, analysis, review, opinion or study relating to the scope, novelty, nonobviousness, patentability, validity, enforceability, value and/or infringement of any claim of the patents at issue, including without limitation:

- a. all documents and communications, samples, prototypes and the like that refer or relate to the first public disclosure, first public use, first advertisement, first offer for sale, and/or the first sale of the alleged invention of the patents at issue in any country, including but not limited to, disclosures, advertisements, offers for sale, and sales of products prior to the priority date, filing date and/or bar date of the patents at issue and concerning use of the subject matter claimed in the patents at issue on or before the respective filing date(s) whether or not you contend such use was not public or was experimental;
- b. all documents and communications concerning the scope and content of the prior art for the patents at issue and any foreign counterparts and all documents identified, found, described, or considered with regard to this prior art, regardless of whether such documents are considered prior art with regard to the patents at issue;
- c. all documents and communications referring or relating to the scope of

the 'art' and/or the level of skill in the 'art,' as the term 'art' is used in 35 U.S.C. § 103, of the subject matters described and claimed in the patents at issue, including all documents concerning the levels of education and experience of persons working in the field, the types of problems encountered in the art, the activities of others, prior art solutions to the problems encountered by the inventor, and the sophistication of the technology at issue;

- d. all documents and communications that refer or relate to seminars, speeches, presentations, lectures, or talks (including, without limitation, texts, drafts and notes thereof) given by any person employed or retained by, or otherwise affiliated with, or under authority or grant from Sanofi (or any predecessor in interest with regard to the patents at issue) concerning alfuzosin formulations or methods of treatment using alfuzosin formulations;
- e. all documents and communications that refer or relate to any papers, articles, or other publications by any person employed or retained by, or otherwise affiliated with, or under the authority or grant by Sanofi, regarding alfuzosin or methods of treatment using alfuzosin formulations, including without limitation all drafts of any such materials and any memoranda or correspondence between co-authors or others concerning either the work reflected in the materials or the publications themselves;
- f. all opinions of counsel concerning the validity, enforceability or infringement of the patents at issue or any foreign counterparts;
- g. all documents and communications that (i) concern, (ii) support or tend to establish and/or otherwise support or (iii) refute or tend to refute any allegation that Apotex or any other person infringed the patents at issue or any foreign counterparts; and
- h. all documents and communications that refer or relate to any oral or written statement made by Sanofi, or any other person or entity, that Sanofi, or any other person, was, is or might be infringing the patents at issue, or that any product made, used or sold by or for Sanofi, or any other person, was, is, or might be infringing the patents at issue.

6. All documents and communications concerning secondary factors or objective indicia of non-obviousness with regard to the patents at issue, including without limitation:

- a. all documents and communications concerning any commercial

success of products covered by the patents at issue and any asserted nexus with the claimed invention;

- b. all documents and communications concerning any long-felt need in the art that was satisfied by the invention claimed in the patents at issue;
- c. all documents and communications concerning whether or not others had tried, but failed to solve the problem solved by the invention claimed in the patents at issue;
- d. all documents and communications concerning simultaneous or near simultaneous invention by others;
- e. all documents and communications concerning whether others have copied the invention claimed in the patents at issue;
- f. all documents and communications concerning any alleged superior, surprising or unexpected results achieved by the invention claimed in the patents at issue; and
- g. all documents and communications concerning whether others have accepted licenses under the patents in suit.

7. All documents and memos concerning or referring to any term extension of the patents at issue.

8. All documents and communications concerning the alleged conception, reduction to practice and development of the alleged invention or inventions claimed by the patents at issue, including without limitation:

- a. all documents concerning any research, development, testing (both animal and human), and/or refinement of the subject matter of the patents at issue;
- b. all documents referring or relating to any research, development, testing (both animal and human) and/or refinement of any commercial embodiments of the subject matter of the patents at issue;
- c. all documents referring or relating to the conception and/or reduction to practice of the alleged invention of the patents at issue;
- d. all documents referring or relating to any Sanofi product that is

believed to be covered literally, or under the doctrine of equivalents, by any claim of the patents at issue; and

- e. all documents concerning, created by, or created under the direction of the inventor named on the face of the patents at issue concerning alfuzosin or method of treatment using alfuzosin.

9. All documents and communications that refer or relate to any contemplated, proposed or actual licenses, or offers for or inquiries regarding license, of any patents, trade secrets or proprietary technology relating to Sanofi's UROXATRAL[®] products, including without limitation:

- a. all documents and communications concerning any request, offer, acquisition or denial of any right (including any forbearance to assert a right), license, agreement, immunity, release, option, title or interest in, to or under the patents at issue, including all documents concerning why an agreement was not consummated (if not consummated), whether any agreement has been terminated, and any documents relating to the transfer and/or assignment of the patents at issue; and
- b. all documents that refer or relate to any licensing policy(ies) of Sanofi and its predecessors-in-interest with regard to the patents at issue and products believed to be covered by the patents at issue.

10. All documents and communications or opinions concerning the value, strategic or pecuniary, of the patents at issue and commercial embodiments of the alleged invention of the patents at issue, including annual marketing reports, actual and estimated sales figures and the like.

11. All documents that compare any element, aspect or attribute of pharmaceutical tablets containing alfuzosin with any element, aspect or attribute of any other product sold anywhere in the world.

12. All documents concerning requests or desires to develop a pharmaceutical tablet containing alfuzosin.

13. All documents concerning requests or desires to develop a method of treatment for dysuria using alfuzosin.

14. All documents and communications concerning Sanofi's corporate structure and organizational policies, including without limitation:

- a. organizational charts that identify all persons involved in research, development, manufacturing, processing, marketing, sales or promotion of UROXATRAL[®] manufactured, marketed or sold by Sanofi;
- b. all documents that constitute, refer or relate to any document retention policy program of Sanofi;
- c. a copy of each of Sanofi's annual reports from its inception to the present; and
- d. all documents and communications concerning development, manufacture, marketing, research and planning concerned with the subject matter of the patents at issue.

15. All documents relating or referring to Sanofi's contemplation or, decision to bring and maintain, a patent infringement lawsuit against Apotex, including without limitation:

- a. all documents constituting or relating to communications with actual or potential purchasers of UROXATRAL[®], or any third party other than an actual or potential purchaser of UROXATRAL[®] relating in anyway to (i) Apotex, (ii) the patents at issue, or (iii) this lawsuit;
- b. all meeting minutes of Sanofi's Board of Directors or any committee of such Board of Directors, and all studies and reports submitted thereto that refer or relate to the Board's authorization to commence litigation charging infringement of the patents at issue, or its consideration of any claims or defenses relating to such litigation;
- c. all documents reflecting Sanofi's knowledge of or belief in, the invalidity and/or enforceability of the patents at issue at the time this action was commenced or at any time thereafter; and
- d. all documents reflecting knowledge by Sanofi and/or any attorney employed or retained by Sanofi who was involved in prosecuting the

applications that ultimately led to the patents at issue or any document or pre-filing activity that constituted or could constitute prior art.

16. All documents, communications, and submissions made by Sanofi or its predecessors-in-interest with regard to the FDA as part of its INDs, NDAs and those portions of the supporting Drug Master File for UROXATRAL[®] products, including but without limitation:

- a. all documents and submissions which contain the product specifications and processing information for the manufacture of UROXATRAL[®], including documents reflecting all starting materials and intermediates, test protocols and certificates of analysis;
- b. all documents and submissions which describe the composition, function and use of UROXATRAL[®];
- c. all documents and submissions which relate to all treatment indications and/or use of UROXATRAL[®], including proposed labeling, proposed package inserts and all other information relating or referring to any proposed or actual clinical use of UROXATRAL[®];
- d. all documents and submissions relating to the composition, formulation, chemistry, functionality or excipients, or other inactive or active ingredients testing and manufacture of UROXATRAL[®]; and
- e. all documents, records, descriptions, agreements, results and product samples relating to the clinical testing of UROXATRAL[®] or earlier versions and formulations of alfuzosin products including all documents and product samples concerning or used in clinical trials resulting in side-effects described in the package insert.

17. NDA 21-287 and all documents and communications concerning NDA 21-287 including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA, and all amendments to such NDA.

18. All NDAs for any other dosage form or drug product containing alfuzosin submitted to the FDA and all documents and communications concerning such NDAs,

including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA and all amendments to such NDA.

19. All documents comprising Plaintiff's Investigation New Drug application ("INDA") for UROXATRAL[®] or any other products containing alfuzosin and all documents and/or communications concerning or referring to that INDA, including but not limited to all clinical testing, protocols and results contained in or referred to in such INDA and all amendments to such INDA.

20. All documents concerning a transfer of any rights or interest in commercial embodiments of the patents at issue from that patents' respective date of conception to the present.

21. All documents and communications evidencing the educational background and qualifications for each of the named inventors of the patents at issue including but not limited to curriculum vitae, resumes, publications, accreditations, honors, awards and/or certificates of recognition.

22. All documents that relate to the research, development and manufacture of pharmaceutical tablets containing alfuzosin, including without limitation:

- a. all documents constituting or relating to any contemplated, proposed or implemented studies, measurements, evaluations, analyses, testing or other compilations of data;
- b. all laboratory notebooks, memoranda, summaries, progress and research reports, meeting minutes, comparative tests or studies;
- c. all documents relating or referring to each actual or proposed change in formulation, composition or process of manufacture of alfuzosin pharmaceutical tablets, from initial stages of development to the present;

- d. all documents relating or referring to each process or method for making pharmaceutical tablets containing alfuzosin, that has been considered, tested, used, or proposed for use by Plaintiff, including but not limited to the process or method by which Plaintiff, or any person or entity acting under Plaintiff's direction or with Plaintiff's authority manufacture pharmaceutical tablets.

23. All documents and communications concerning the research and/or development of any medicines containing alfuzosin in pharmaceutical tablets, including but not limited to laboratory notebooks, invention records, research results, studies, tests, memoranda, project status reports, forecasts and projections.

24. All documents in Plaintiff's possession, custody or control which discuss pharmaceutical tablets containing alfuzosin.

25. All documents in Plaintiff's possession, custody or control which discuss a method for treatment of dysuria using alfuzosin.

26. All documents or communications concerning, discussing or expressing any complaints, concerns or dissatisfaction with any aspect, element or feature of any products or formulations containing alfuzosin.

27. All communications by and between Jagotec AG and Sanofi relating to pharmaceutical tablets containing alfuzosin including but not limited to documents relating to the '940 patent.

28. All documents and communications by and between Sythelabo, Sanofi-Synthelabo, Jagotec AG, Jagotech AB, and Sanofi-Aventis, including but not limited to all assignments and any other documents referring to the assignments or to which the assignments refer.

29. All documents that refer or relate to the decision to develop or the development of a pharmaceutical tablet for oral administration and for the controlled

release of alfuzosin or a salt thereof.

30. All documents referring or relating to a method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human, including the development and efficacy of such method.

31. Please provide all documents concerning, analyzing, evaluating or referring to any and all of the following documents:

- a. Cavero et al., *Br. J. Pharmacol.*, Vol. 81, *Alfuzosin (SL 77.499), A New Antihypertensive Agent with A Peripheral Site of Action : II. In Vitro Pharmacological Studies* ;
- b. Cavero et al., *Fed. Proc.*, Vol. 43, No. 3, *Alfuzosin, Antihypertensive Agent With α -Adrenoceptor Antagonist Properties*, abstract 2627 (1984);
- c. Hedlund et al., *The Journal of Urology*, Vol. 133, *Effects of Prazosin in Patients With Benign Prostatic Obstruction*, Pgs 275-78 (1983);
- d. Ronchi et al., *Urological Research*, Vol. 10, No. 3, *Symptomatic Treatment of Benign Prostatic Obstruction with Nicergoline: A Placebo Controlled Clinical Study and Urodynamic Evaluation*, pgs. 131-34 (1982);
- e. Whitefield et al., *Br. J. Pharmacol.*, Vol. 47, *the Effect of Adrenergic Blocking Drugs on Outflow Resistance*, Pgs. 823-27 (1976);

32. All documents produced or to be produced by Sanofi to opposing parties in any and all earlier filed or pending litigations relating to the patents at issue, including but not limited to documents produced by Sanofi in connection with the following cases: *Sanofi-Aventis et al v. Actavis South Atlantic LLC, et al* (Case No. 1:07-cv-00572); and *Sanofi-Aventis et al v. Barr Laboratories Inc.* (1:07-cv-00574).

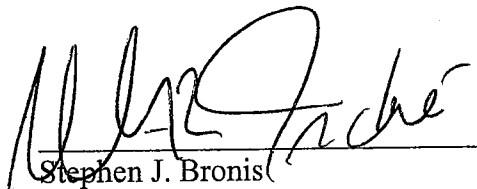
33. All documents that have been disclosed or provided to any individual by, any scientist and/or consultant retained by Plaintiff in connection with the above-

captioned action.

34. All documents relating to any investigation or test conducted by any scientist and/or consultant retained by Plaintiff in the above-captioned action.

35. All documents that Plaintiff may use as an exhibit in any trial, hearing, submission to the court or deposition in the above-captioned action.

Dated: January 18, 2008



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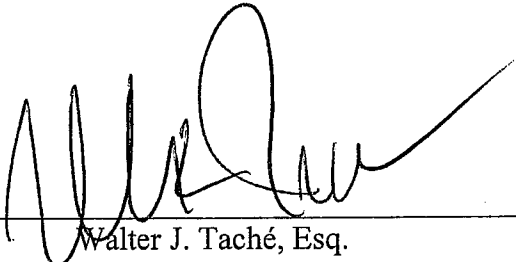
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by hand on January 18, 2008, to:

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Walter J. Taché, Esq.

EXHIBIT X

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

DEFENDANTS' FIRST SET OF INTERROGATORIES TO PLAINTIFFS

Pursuant to Federal Rules of Civil Procedure 33, Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Defendant"), through counsel, hereby request that Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. L.L.C. (collectively "Sanofi" or "Plaintiff"), answer in writing within thirty (30) days of the date of service of these interrogatories.

A Protective Order has not yet been entered in this case. Apotex agrees to treat all answers as Attorneys Eyes Only until a Protective Order is entered by the Court.

DEFINITIONS AND INSTRUCTIONS

A. **Parties.** The terms "plaintiff" and "defendants" as well as a party's full or abbreviated name or a pronoun referring to a party mean the party and, where applicable, its officers, directors, employees, partners, corporate parent, subsidiaries, affiliates, or predecessors in interest. This definition is not intended to impose a discovery obligation on any person who is not a party to the litigation unless that person

is obligated to co-operate with Sanofi with regard to the instant action.

B. **Communication.** The term "communication" means the transmittal of information in the form of facts, ideas, inquiries, or otherwise.

C. **Concern(s), Concerning, Concerned with, Relate(s) or Relating to.** The terms "concern(s)," "concerning," "concerned with," "relates," or "relating to" are used interchangeably and mean concerning, evidencing, pertaining to, referring to, mentioning, memorializing, commenting on, containing, identifying, connected with, contemplating, discussing, stating, describing, reflecting, dealing with, consisting of, constituting, comprising, recording, or being relevant to all or any portion of the specified fact, conditions, events or incidents.

D. **Date.** The term "Date" means the exact day, month and year, if known or ascertainable, or, if not, the best approximation possible (including the temporal relationship to other events).

E. **Document.** The term "document" shall mean every means of recording any form of communication or representation upon any tangible thing, including letters, numbers, words, pictures, sounds, or symbols, or combinations thereof, whether recorded by handwriting, printing, photostatic, or photographic means, electronically stored information, including information stored on magnetic impulse, tape, computer disk, CD-ROM or any other form of data storage, data compilation, or mechanical or electronic recording, and all other tangible things which come within the meaning of writing contained in Rule 1001 of the Federal Rules of Evidence, or within the meaning of "document" or "tangible thing" contained in Rule 34 of the Federal Rules of Civil Procedure.

F. **Person.** The term “person” is defined as any natural person or any business, legal or governmental entity or association, and any functional division thereof.

G. **Describe.** The term “describe” means to provide a narrative statement or description, phrased in specifics, of facts or matters to which the interrogatory refers in full and complete detail, including, but not limited to, an identification of all persons, communication, acts, transactions, events, agreements, recommendations, and documents used, necessary or desirable to make such statement or description full and complete.

H. **Identify.** The term “identify” shall mean:

- i. When used with respect to an individual or natural person, to state:
 1. the person’s full name;
 2. any other name used by that person presently or in the past;
 3. the person’s present or last known address, residence address, and telephone numbers; and
 4. the corporation, partnership, association, foundation, trust, organization or other entity, and the functional division thereof, with which the person is now associated, and the person’s title, status, position, rank or classification with such entity at the present and throughout the time period specified.
- ii. When used with respect to a person other than a natural person, including but not limited to, any corporation, partnership, association, foundation, trust, organization, or other entity or functional division thereof, to state:
 1. its full name;
 2. the address of its principal office or place of business;
 3. all names under which it is doing business or ever has done business;

4. the nature of the venture (e.g. sole proprietorship, partnership, corporation, etc.); and

5. the identities of its officers, directors, partners or administrators.

iii. When used with respect to a communication to:

1. state the dates and places of origin and reception of such communication;

2. identify each person who was present at, or participated in, such communication;

3. identify the type of communication (e.g. letter, facsimile transmission, face-to-face conversation, telephone conversation, etc.);

4. describe in full and complete detail the substance of each such communication; and

5. identify each document which records, shows, or otherwise indicates the substance of such communication.

iv. When used with respect to a document or tangible thing, to state:

1. the type of document or tangible thing (e.g. letter, memoranda, computer disk, etc.);

2. the number of pages of which it consists where appropriate;

3. the date it was created (if no date appears, the response shall so state and shall supply the date or approximate date that such document or thing was created);

4. its author and signatories;

5. its addresses and all other persons receiving copies;

6. the nature and substance of the document with sufficient particularity to enable it to be identified; and

7. its location and its custody (or if it is no longer within your possession, custody or control, state what disposition was made of it; state the date such disposition; identify each

person who participated in or approved such disposition; and identify the person or persons having knowledge of its contents). In lieu of identifying documents and things in the foregoing manner, defendant may identify them by document number and produce such documents for inspection pursuant to Federal Rule of Civil Procedure 33(c).

v. When used with respect to a fact to:

1. describe the fact;
2. state when it became known;
3. identify the course from which the fact was learned;
4. identify documents that record, show or otherwise indicate the fact; and
5. state why the fact is believed true.

I. **Alfuzosin.** The term “Alfuzosin” or “Alfuzosine” is defined as the drug compound of this name identified in the '940 or '491 patents, including any compound of the formula N-[3-[(4-amino-6,7-dimethoxy-quinazolin-2-yl)-methyl-amino]propyl] tetrahydrofuran-2-carboxamide and any salts thereof.

J. **State the factual and legal basis.** When an interrogatory calls upon a party to “state the factual and legal basis” of or for a particular claim, assertion, allegation, or contention, the party shall:

- i. specifically identify each and every document (and, where pertinent, the section, article, or subparagraph thereof), which forms any part of the source of the party’s information regarding the alleged facts or legal conclusions referred to by the interrogatory;
- ii. identify each and every communication which forms any part of the source of the party’s information regarding the alleged facts or legal conclusions referred to by the interrogatory;

- iii. state separately the acts or omissions to act on the part of any person (identifying the acts or omissions to act by stating their nature, time, and place and identifying the persons involved) which form any part of the party's information regarding the alleged facts or legal conclusions referred to in the interrogatory; and
- iv. state separately any other fact that forms the basis of the party's information regarding the alleged facts or conclusions referred to in the interrogatory.

K. The following **rules of construction** apply to these interrogatories, definitions, and instructions:

- i. **All/Each/Any.** The terms "all," "each," and "any" shall be construed as inclusive and synonymous and are as inclusive in scope as permitted by the Federal Rules of Civil Procedure.
- ii. **And/Or.** The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside the scope.
- iii. **Number.** The use of the singular form of any word includes the plural and vice versa.
- iv. **Independence.** Except as otherwise expressly directed herein, each paragraph and subparagraph of an interrogatory and/or document request shall be construed independently and not by reference to any other paragraph or subparagraph herein for the purpose of limiting the scope of the interrogatory and/or document request being responded to.

L. If Plaintiff finds the meaning of any terms in these interrogatories unclear, Plaintiff shall assume a reasonable meaning, state what the assumed meaning is, and respond to the interrogatory according to the assumed meaning.

M. If Plaintiff objects to any interrogatory or part of any interrogatory, the reason(s) for the objection shall be stated in full. If an objection is made to any interrogatory, responses should be to any part of the interrogatory to which the objection

does not relate.

N. If any information, document or thing responsive to any of the following interrogatories are withheld on the basis of privilege and/or work-product doctrine, the following information is requested with respect to any such refusal:

- i. the privilege and/or work-product rule of law being relied upon;
- ii. the date the document was created;
- iii. the identity of the person or persons who created the information, document, or thing;
- iv. the identity of the present custodian of the information, document, or thing;
- v. the addressee(s) and all other recipients of the information, document, or thing;
- vi. the subject matter of the information, document or thing; and
- vii. the location of the information, document or thing.

O. **The '940 Patent.** The term "the '940 Patent" means U.S. Patent No. 6,149,940.

P. **The '491 Patent.** The term "the '491 Patent" means U.S. Patent No. 4,661,491.

Q. **Patents at Issue.** The term "patents at issue" means U.S. Patent No. 6,149,940 and U.S. Patent No. 4,661,491.

These interrogatories are continuing in nature pursuant to Rule 26(e), Fed. R. Civ. P., and require timely supplementation of information as they come within Sanofi's possession custody and control.

INSTRUCTIONS

1. In responding to these Interrogatories, the Plaintiff is requested to furnish all information known or available to plaintiff, regardless of whether such information is directly in its possession or that of its representative, attorneys, experts, as well as its respective agents, employees or representatives.

2. If plaintiff cannot answer an interrogatory completely, plaintiff shall answer to the extent possible, specifying the ways in which the response may be incomplete and stating the substance of its knowledge, information and belief concerning the subject matter of the unanswered portion.

3. If plaintiff finds the meaning of any terms in these interrogatories unclear, plaintiff shall assume a reasonable meaning, state what the assumed meaning is, and respond to the interrogatory according to the assumed meaning.

4. These interrogatories are continuing in nature so as to require prompt supplemental answers if plaintiff, directly or indirectly, obtains further or different information relative thereto, after the answers to interrogatories are served, or plaintiff learns that the answers to the interrogatories served are not full, complete, and/or correct, as required by Rule 26(e) of the Federal Rules of Civil Procedure.

INTERROGATORIES

1. Identify by name, address and telephone number all persons or entities previously owning any right, title or interest in the '491 patent or '940 patent.

2. State the basis for Plaintiffs' contention that this is an exceptional case under § 285 and that Plaintiffs' are entitled to an award of attorney's fees as stated in Plaintiffs' Complaint (Civil No. 07-61800).

3. Describe in full and complete detail the level of ordinary skill of the art for the patents at issue, including the educational level of the inventor, the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field.

4. Identify any terms in the patents at issue that Plaintiffs will seek to have construed by the Court, including any terms that you contend were specifically defined in the specification or otherwise should be construed differently from their ordinary meaning, stating the definition you ascribe to those terms and the basis for your proposed definition.

5. Describe the problem(s), if any, Plaintiffs contend was solved by the subject matter claimed in the patents at issue.

6. Describe in full and complete detail any and all differences Plaintiffs contend exist between the subject matter claimed in the patents at issue and the prior art.

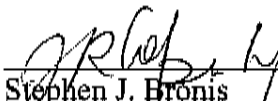
7. Identify which claims of the '491 patent Plaintiffs contend are infringed by the Apotex parties, and the factual and legal basis for those contentions.

8. Describe in full and complete detail any and all secondary considerations/objective indicia that you contend tend to show the subject matter claimed in the '491 patent would not have been obvious.

9. Identify all prior art for the '491 patent known to Francois Regnier, Helmuth Wegner, Michael Alexander, Paul Darkes, William E. Player, or any other person substantively involved in the prosecution of the '491 patent as of May 28, 1985

10. Identify all prior art for the '940 patent known to Laretta Maggi, Ubaldo

Conte, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau, Clemence Rauch-Desanti, D. Douglas Price, Elisabeth Thouret-Lemaitre, Harvey Jacobson, or any other person substantively involved in the prosecution of the '940 patent as of August 29, 1996.



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Attorneys for Apotex Corp and Apotex Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by fax and mail on February 8, 2008, to:

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Jennifer Coberly

EXHIBIT Y

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

**PLAINTIFFS' RESPONSES AND OBJECTIONS TO DEFENDANTS' FIRST REQUEST
FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFF**

Pursuant to Federal Rules of Civil Procedure 26 and 34 and Local Rules 26.1 and 34.1 for the Southern District of Florida, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") make the following objections and responses to Defendants Apotex Inc. and Apotex Corp.'s (collectively "Apotex") First Request For Production Of Documents And Things To Plaintiff.

Pursuant to Federal Rule of Civil Procedure 26(e), sanofi-aventis reserves the right to supplement its responses and objections as discovery and its investigation continues.

**PLAINTIFFS' GENERAL OBJECTIONS TO DEFENDANTS' FIRST REQUEST FOR
PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFFS**

Sanofi-aventis makes the following general objections to Defendants' First Request For Production Of Documents And Things To Plaintiff ("General Objections"), which General

Objections are hereby incorporated by reference and made part of its response to each such request:

1. Sanofi-aventis objects to each request to the extent that it seeks to impose requirements or obligations on sanofi-aventis in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

2. Sanofi-aventis objects to Apotex's "Definitions and Instructions" to the extent that they purport to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

3. Sanofi-aventis objects to Apotex's "Definitions and Instructions" to the extent that they purport to alter the plain meaning or scope of any request, on the ground that such alteration renders the request vague, ambiguous and uncertain.

4. Sanofi-aventis objects to Apotex's definition of "Parties" as overly broad to the extent that it purports to include individuals, corporations or entities over which sanofi-aventis has no control or are not otherwise parties to the present action.

5. Sanofi-aventis objects to Apotex's definition of "Communication" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

6. Sanofi-aventis objects to Apotex's definitions of "Concern(s)," "Concerning," "Concerned with," "Relate(s)," and "Relating to" as vague and ambiguous and, to the extent understood, to the extent that they purport to impose obligations or requirements in addition to or

different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

7. Sanofi-aventis objects to Apotex's definition of "Date" as overly broad and unduly burdensome and unlikely to lead to the discovery of admissible evidence, and to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

8. Sanofi-aventis objects to Apotex's definition of "Document" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

9. Sanofi-aventis objects to Apotex's definition of "Person" to the extent that it purports to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

10. Sanofi-aventis objects to Apotex's "rules of construction" to the extent that they purport to impose obligations or requirements in addition to or different from those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

11. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as overly broad and unduly burdensome to the extent that they seek "All," "Each," or "Any" document or thing requested, and thus purport to impose obligations in addition to, or different from, those imposed by the Federal Rules of Civil Procedure or the Local Rules for the Southern District of Florida.

12. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are

protected by the attorney-client privilege, attorney work-product doctrine, or any other applicable privilege or immunity. Nothing contained in these objections and responses is intended to be, or in any way constitutes, a waiver of any such applicable privilege or immunity.

13. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are not in sanofi-aventis's possession, custody or control.

14. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are in the possession, custody or control of Jagotec AG.

15. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents and things that contain confidential information of third parties.

16. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that the requests are duplicative in nature.

17. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as vague, ambiguous and uncertain to the extent that they seek information, documents or things that are not described with reasonable particularity.

18. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are not relevant to the claims or defenses of any party, nor reasonably calculated to lead to the discovery of admissible evidence.

19. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they seek information, documents or things that are subject to either the European Union and/or member states privacy directives.

20. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff to the extent that they purport to seek documents, things or information generated after June 12, 2007, the date upon which sanofi-aventis first received written notification that an Abbreviated New Drug Application had been filed with the FDA seeking FDA approval for the commercial manufacture, use, offer for sale and sale of a generic version of sanofi-aventis's Uroxatral® brand product. Except for information related to secondary indicia of non-obviousness, sanofi-aventis will not provide any information generated after June 12, 2007 unless and until Apotex demonstrates the purported relevance of such information and/or how it is reasonably calculated to lead to the discovery of admissible evidence.

21. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they purport to require sanofi-aventis to produce information prior to: this Court's decisions on sanofi-aventis's Motion to Transfer or Stay, Motion for Protective Order and Apotex's Motion for Entry of a Protective Order; the Judicial Panel on Multidistrict Litigation's decision on sanofi-aventis's Motion to Transfer and Consolidate for Pretrial Proceedings; and/or the Delaware Court's decision on Apotex's Motion to Transfer in Favor of Pending Florida Jurisdiction or in the Alternative Stay the Delaware Litigation (collectively "the currently pending motions").

22. Sanofi-aventis objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they seek information, documents or things that contain trade secret or other confidential, research, development or commercial information prior

to the entry of an agreed upon Protective Order in this action. Sanofi-aventis further objects to Apotex's First Request for Production of Documents and Things to Plaintiff as premature to the extent that they purport to require sanofi-aventis to produce information prior to the Court's decision on Apotex's Motion for Entry of a Protective Order.

REQUEST NO. 1:

All documents concerning any proposal, consideration or decision by Plaintiff to draft and/or file the patents at issue.

RESPONSE TO REQUEST NO. 1:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "proposal" and "consideration."

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 2:

All documents reviewed and/or relied on by Plaintiff in making the determination to seek patent protection for the subject matter of the patents at issue.

RESPONSE TO REQUEST NO. 2:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 3:

All documents which are relevant to establishing a date of invention by Plaintiff, or any person associated with Plaintiff, earlier than the filing date for each of the patents at issue.

RESPONSE TO REQUEST NO. 3:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 4:

All documents and communications that refer or relate to the preparation and/or prosecution of the patents at issue and/or any U.S. applications or foreign applications that constitute or are based in whole or in part on, or which claim priority from, or are the basis of priority for, any of the applications in the family of patent applications leading to the patents at issue and any related oppositions, re-examinations, and/or reissue proceedings including, without limitation:

- a. all documents that provided the bases for any of said applications or proceedings;
- b. all files in Plaintiff's possession, custody or control regarding the patents at issue, the patent applications for the patents at issue, or any related U.S. or foreign patents or applications;
- c. all disclosures of the subject matter of any of said applications or proceedings;

- d. all communications between the alleged inventor and his patent attorney(s) or agent(s) concerning the subject matter described or claimed in any of said applications or proceedings;
- e. all documents referring or relating to any information used or supplied by the alleged inventor in connection with the preparation or prosecution of any of said applications or proceedings including invention disclosure prepared by or for the inventor;
- f. all drafts of any said applications or proceedings;
- g. all patents, publications, references or prior art, and all records or documents referring or relating to any prior art or possible prior art, and all records or documents referring or relating to any prior art or any possible ground of unpatentability and/or invalidity, submitted, cited, discussed or considered in connection with any of said applications or proceedings;
- h. all documents referring or relating to the citation of, decision not to cite, or failure to cite, any references and/or prior art to the PTO or other patent office or patent authority in connection with said applications or proceedings; and
- i. all copies (including drafts) of responses to Office Actions, amendments, affidavits, declarations and other communications or submissions of any kind with or to the PTO or other patent office, or patent authority with respect to any of said applications or proceedings.

RESPONSE TO REQUEST NO. 4:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts, as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term “possible prior art.”

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 5:

All documents and communications concerning any search, investigation, analysis, review, opinion or study relating to the scope, novelty, nonobviousness, patentability, validity, enforceability, value and/or infringement of any claim of the patents at issue, including without limitation:

- a. all documents and communications, samples, prototypes and the like that refer or relate to the first public disclosure, first public use, first advertisement, first offer for sale, and/or the first sale of the alleged invention of the patents at issue in any country, including but not limited to, disclosures, advertisements, offers for sale, and sales of products prior to the priority date, filing date and/or bar date of the

patents at issue and concerning use of the subject matter claimed in the patents at issue on or before the respective filing dates(s) whether or not you contend such use was not public or was experimental;

- b. all documents and communications concerning the scope and content of the prior art for the patents at issue and any foreign counterparts and all documents identified, found, described, or considered with regard to this prior art, regardless of whether such documents are considered prior art with regard to the patents at issue;
- c. all documents and communications referring or relating to the scope of the 'art' and/or the level of skill in the 'art,' as the term 'art' is used in 35 U.S.C. § 103, of the subject matters described and claimed in the patents at issue, including all documents concerning the levels of education and experience of persons working in the field, the types of problems encountered in the art, the activities of others, prior art solutions to the problems encountered by the inventor, and the sophistication of the technology at issue;
- d. all documents and communications that refer or relate to seminars, speeches, presentations, lectures, or talks (including without limitation, texts, drafts and notes thereof) given by any person employed or retained by, or otherwise affiliated with, or under authority or grant from Sanofi (or any predecessor in interest with regard to the patents at issue) concerning alfuzosin formulations or methods of treatment using alfuzosin formulations;
- e. all documents and communications that refer or relate to any papers, articles, or other publications by any person employed or retained by, or otherwise affiliated with, or under the authority or grant by Sanofi, regarding alfuzosin or methods of treatment using alfuzosin formulations, including without limitation all drafts of any such materials and any memoranda or correspondence between co-authors or others concerning either the work reflected in the materials or the publications themselves;
- f. all opinions of counsel concerning the validity, enforceability or infringement of the patents at issue or any foreign counterparts;
- g. all documents and communications that (i) concern, (ii) support or tend to establish and/or otherwise support or (iii) refute or tend to refute any allegation that Apotex or any other person infringed the patents at issue or any foreign counterparts; and
- h. all documents and communications that refer or relate to any oral or written statement made by Sanofi, or any other person or entity, that Sanofi, or any other person, was, is or might be infringing the patents at issue, or that any product made, used or sold by or for Sanofi, or any other person, was is, or might be infringing the patents at issue.

RESPONSE TO REQUEST NO. 5:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request, and in particular to the over-breadth of subsection “d”, as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis’s possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term “and the like.” Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to its request for “prior art . . . regardless of whether such documents are considered prior art with regard to the patents at issue.” Sanofi-aventis also objects to this request, to the extent it seeks documents concerning foreign counterparts or documents related to

the first public disclosure, first public use, first advertisement, first offer for sale and/or the first sale “in any country”, as overly broad and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 6:

All documents and communications concerning secondary factors or objective indicia of non-obviousness with regard to the patents at issue, including without limitation:

- a. all documents and communications concerning any commercial success of products covered by the patents at issue and any asserted nexus with the claimed invention;
- b. all documents and communications concerning any long-felt need in the art that was satisfied by the invention claimed in the patents at issue;
- c. all documents and communications concerning whether or not others had tried, but failed to solve the problem solved by the invention claimed in the patents at issue;
- d. all documents and communications concerning simultaneous or near simultaneous invention by others;

- e. all documents and communications concerning whether others have copied the invention claimed in the patents at issue;
- f. all documents and communications concerning any alleged superior, surprising or unexpected results achieved by the invention claimed in the patents at issue; and
- g. all documents and communications concerning whether others have accepted licenses under patents in suit.

RESPONSE TO REQUEST NO. 6:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 7:

All documents and memos concerning or referring to any term extension of the patents at issue.

RESPONSE TO REQUEST NO. 7:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 8:

All documents and communications concerning the alleged conception, reduction to practice and development of the alleged invention or inventions claimed by the patents at issue, including without limitation:

- a. all documents concerning any research, development, testing (both animal and human), and/or refinement of the subject matter of the patents at issue;
- b. all documents referring or relating to any research, development, testing (both animal and human) and/or refinement of any commercial embodiments of the subject matter of the patents at issue;
- c. all documents referring or relating to the conception and/or reduction to practice of the alleged invention of the patents at issue;
- d. all documents referring or relating to any Sanofi product that is believed to be covered literally, or under the doctrine of equivalents, by any claim of the patents at issue; and
- e. all documents concerning, created by, or created under the direction of the inventor named on the face of the patents at issue concerning alfuzosin or method of treatment using alfuzosin.

RESPONSE TO REQUEST NO. 8:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-

aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested, including but not limited to all documents and things concerning the testing of Uroxatral®. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term “refinement.” Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 9:

All documents and communications that refer or relate to any contemplated, proposed or actual license, or offers for or inquiries regarding license, of any patents, trade secrets or proprietary technology relating to Sanofi’s UROXATRAL® products, including without limitation:

- a. all documents and communications concerning any request, offer, acquisition or denial of any right (including any forbearance to assert a right), license, agreement, immunity, release, option, title or interest in, to or under the patents at issue, including all documents concerning why an agreement was not consummated (if not consummated), whether any agreement has been terminated, and any documents relating to the transfer and/or assignment of the patents at issue; and
- b. all documents that refer or relate to any licensing policy(ies) of Sanofi and its predecessors-in-interest with regard to the patents at issue and products believed to be covered by the patents at issue.

RESPONSE TO REQUEST NO. 9:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to the licensing of the patents at issue and sanofi-aventis's licensing policies regarding the patents at issue, within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 10:

All document and communications or opinions concerning the value, strategic or pecuniary, of the patents at issue and commercial embodiments of the alleged invention of the patents at issue, including annual marketing reports, actual and estimated sales figures and the like.

RESPONSE TO REQUEST NO. 10:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms “strategic,” “pecuniary” and “and the like.”. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis’s possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order,

sanofi-aventis will produce relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate any relevant aspects of the marketing and sales of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 11:

All documents that compare any element, aspect or attribute of pharmaceutical tablets containing alfuzosin with any element, aspect or attribute of any other product sold anywhere in the world.

RESPONSE TO REQUEST NO. 11:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis

objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis also objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms “element,” “aspect,” and “attribute.” Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control related to Uroxatral® that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 12:

All documents concerning requests or desires to develop a pharmaceutical tablet containing alfuzosin.

RESPONSE TO REQUEST NO. 12:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the

production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "requests" and "desires.". Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control related to Uroxatral® that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 13:

All documents concerning requests or desires to develop a method of treatment for dysuria using alfuzosin.

RESPONSE TO REQUEST NO. 13:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation

and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms "requests" and "desires".

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 14:

All documents and communications concerning Sanofi's corporate structure and organizational policies, including without limitation:

- a. organizational charts that identify all persons involved in research, development, manufacturing, processing, marketing, sales or promotion of UROXATRAL® manufactured, marketed or sold by Sanofi;
- b. all documents that constitute, refer or relate to any document retention policy program of Sanofi;
- c. a copy of each of Sanofi's annual reports from its inception to the present; and
- d. all documents and communications concerning development, manufacture, marketing, research and planning concerned with the subject matter of the patents at issue.

RESPONSE TO REQUEST NO. 14:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it does not restrict the date range for the documents or things concerning the categories requested. Sanofi-aventis objects to this request as vague, ambiguous

and uncertain, particularly with respect to the undefined term “processing.” Sanofi-aventis also objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacture, production, or distribution of Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce: representative organizational charts; documents sufficient to demonstrate sanofi-aventis’s document retention policies; and relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate any relevant aspects of the research, development, marketing, sales and promotion of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 15:

All documents relating or referring to Sanofi’s contemplation or, decision to bring and maintain, a patent infringement lawsuit against Apotex, including without limitation:

- a. all documents constituting or relating to communications with actual or potential purchasers of UROXATRAL® , or any third party other than an actual or potential purchaser of UROXATRAL® relating in anyway to (i) Apotex, (ii) the patents at issue, or (iii) this lawsuit;
- b. all meeting minutes of Sanofi’s Board of Directors or any committee of such Board of Directors, and all studies and reports submitted thereto that refer or relate to the Board’s authorization to commence litigation charging infringement of the patents at issue, or its consideration of any claims or defenses relating to such litigation;

- c. all documents reflecting Sanofi's knowledge of or belief in, the invalidity and/or enforceability of the patents at issue at the time this action was commenced or at any time thereafter; and
- d. all documents reflecting knowledge by Sanofi and/or any attorney employed or retained by Sanofi who was involved in prosecuting the applications that ultimately led to the patents at issue or any document or pre-filing activity that constituted or could constitute prior art.

RESPONSE TO REQUEST NO. 15:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 16:

All documents, communications, and submissions made by Sanofi or its predecessors-in-interest with regard to the FDA as part of its INDA, NDA and those portions of the supporting Drug Master File for UROXATRAL® products, including but without limitation:

- a. all documents and submissions which contain the product specifications and processing information for the manufacture of UROXATRAL®, including documents reflecting all starting materials and intermediates, test protocols and certificates of analysis;
- b. all documents and submissions which describe the composition, function and use of UROXATRAL®;
- c. all documents and submissions which relate to all treatment indications and/or use of UROXATRAL®, including proposed labeling, proposed package inserts and all other information relating or referring to any proposed or actual clinical use of UROXATRAL®;
- d. all documents and submissions relating to the composition, formulation, chemistry, functionality or excipients, or other inactive or active ingredients testing and manufacture of UROXATRAL®; and
- e. all documents, records, descriptions, agreements, results and product samples relating to the clinical testing of UROXATRAL® or earlier versions and formulations of alfuzosin products including all documents and product samples concerning or used in clinical trials resulting in side-effects described in the package insert.

RESPONSE TO REQUEST NO. 16:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client

privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of INDA 51,200 and/or NDA 21-287 and documents relating to INDA 51,200 and/or NDA 21-287 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 17:

NDA 21-287 and all documents and communications concerning NDA 21-287 including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA, and all amendments to such NDA.

RESPONSE TO REQUEST NO. 17:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly

burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of NDA 21-287 and documents relating to NDA 21-287 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 18:

All NDAs for any other dosage form or drug product containing alfuzosin submitted to the FDA and all documents and communications concerning such NDAs, including but not limited to all communications and correspondence with the FDA concerning such NDA, all clinical testing, protocols and results contained in or referred to in such NDA and all amendments to such NDA.

RESPONSE TO REQUEST NO. 18:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by NDA 21-287 and/or ANDA 79-013. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

REQUEST NO. 19:

All documents comprising Plaintiff's Investigation New Drug application ("INDA") for UROXATRAL® or any other products containing alfuzosin and all documents and/or communications concerning or referring to that INDA, including but not limited to all clinical testing, protocols and results contained in or referred to in such INDA and all amendments to such INDA.

RESPONSE TO REQUEST NO. 19:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by INDA 51,200. Sanofi-aventis additionally objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to

lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®. Sanofi-aventis objects to this request to the extent that it seeks regulatory documents located outside of the United States and/or foreign regulatory filings.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant excerpts of INDA 51,200 and documents relating to INDA 51,200 that were submitted to the FDA to the extent that such documents or excerpts do not include individual patient data provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 20:

All documents concerning a transfer of any rights or interest in commercial embodiments of the patents at issue from that patents' respective date of conception to the present.

RESPONSE TO REQUEST NO. 20:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 21

All documents and communications evidencing the educational background and qualifications for each or the named inventors of the patents at issue including but not limited to curriculum vitae, resumes, publications, accreditations, honors, awards and/or certificates of recognition.

RESPONSE TO REQUEST NO. 21:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control. Sanofi-

aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis’s possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 22:

All documents that relate to the research, development and manufacture of pharmaceutical tablets containing alfuzosin, including without limitation;

- a. all documents constituting or relating to any contemplated, proposed or implemented studies, measurements, evaluations, analyses, testing or other compilations of data;
- b. all laboratory notebooks, memoranda, summaries, progress and research reports, meeting minutes, comparative tests or studies;
- c. all documents relating or referring to each actual or proposed change in formulation, composition or process of manufacture of alfuzosin pharmaceutical tablets, from initial stages of development to the present;
- d. all documents relating or referring to each process or method for making pharmaceutical tablets containing alfuzosin, that has been considered, tested,

used, or proposed for use by Plaintiff, including but not limited to the process or method by which Plaintiff, or any person or entity acting under Plaintiff's direction or with Plaintiff's authority manufacture pharmaceutical tablets.

RESPONSE TO REQUEST NO. 22:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral® and/or dysuria. Sanofi-aventis also objects to this request as overly broad and irrelevant to the extent it requests documents and things concerning the testing, manufacturing process, or production of Uroxatral® or a treatment for dysuria.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce relevant, responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, sufficient to demonstrate the research and development of Uroxatral® provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 23:

All documents and communications concerning the research and/or development of any medicines containing alfuzosin in pharmaceutical tablets, including but not limited to laboratory notebooks, invention records, research results, studies, tests, memoranda, project status reports, forecasts and projections.

RESPONSE TO REQUEST NO. 23:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-

aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term “medicines.” Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 24:

All documents in Plaintiff’s possession, custody or control which discuss pharmaceutical tablets containing alfuzosin.

RESPONSE TO REQUEST NO. 24:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis’s possession,

custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 25:

All documents in Plaintiff’s possession, custody or control which discuss a method for treatment of dysuria using alfuzosin.

RESPONSE TO REQUEST NO. 25:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly

burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 26:

All documents or communications concerning, discussing or expressing any complaints, concerns or dissatisfaction with any aspect, element or feature of any products or formulations containing alfuzosin.

RESPONSE TO REQUEST NO. 26:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis’s possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined terms “complaints,” “concerns,” “dissatisfaction.” Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to

lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control sufficient to show consumer complaints to the extent that such documents or excerpts do not include individual patient data that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 27:

All communications by and between Jagotec AG and Sanofi relating to pharmaceutical tablets containing alfuzosin including but not limited to documents relating to the '940 patent.

RESPONSE TO REQUEST NO. 27:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or

things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 28:

All documents and communications by and between Synthelabo, Sanofi-Synthelabo, Jagotec AG, Jagotec AB, and Sanofi-Aventis, including but not limited to all assignments and any other documents referring to the assignments or to which the assignments refer.

RESPONSE TO REQUEST NO. 28:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of

admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 29:

All documents that refer or relate to the decision to develop or the development of a pharmaceutical tablet for oral administration and for the controlled release of alfuzosin or a salt thereof.

RESPONSE TO REQUEST NO. 29:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis's possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis objects to this request as overly broad and unduly burdensome to the extent that it seeks "all" documents or things concerning the categories requested. Sanofi-aventis objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents not related to Uroxatral®.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents related to Uroxatral® within

its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 30:

All documents referring or relating to a method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human, including the development and efficacy of such method.

RESPONSE TO REQUEST NO. 30:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and therefore are of no greater burden for Apotex to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody

or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 31:

Please provide all documents concerning, analyzing, evaluating or referring to any and all of the following documents:

- a. Cavero et al., *Br. J. Pharmacol.*, Vol. 81, *Alfuzosin (SL 77,499), A new Antihypertensive Agent with A Peripheral Site of Action : II. In Vitro Pharmacological Studies* ;
- b. Cavero et al., *Fed. Proc.*, Vol. 43, No. 3, *Alfuzosin, Antihypertensive Agent With a-Adrenoceptor Antagonist Properties*, abstract 2627 (1984);
- c. Hedlund et al., *The Journal of Urology*, Vol. 133, *Effects of Prazosin in Patients With Benign Prostatic Obstruction*, Pgs 275-78 (1983);
- d. Ronchi et al., *Urological Research*, Vol. 10, No. 3, *Symptomatic Treatment of Benign Prostatic Obstruction with Nicergoline: A Placebo Controlled Clinical Study and Urodynamic Evaluation*, pgs. 131-34 (1982);
- e. Whitefield et al., *Br. J. Pharmacol.*, Vol. 47, *the Effect of Adrenergic Blocking Drugs on Outflow Resistance*, Pgs. 823-27 (1976);

RESPONSE TO REQUEST NO. 31:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as overly broad and unduly burdensome to the extent that it seeks “all” documents or

things concerning the categories requested. Sanofi-aventis objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce. Sanofi-aventis additionally objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term “evaluating”.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 32:

All documents produced or to be produced by Sanofi to opposing parties in any and all earlier filed or pending litigations relating to the patents at issue, including but not limited to documents produced by Sanofi in connection with the following cases: *Sanofi-Aventis et al v. Actavis South Atlantic LLC, et al* (Case No. 1:07-cv-00572); and *Sanofi-Aventis et al v. Barr Laboratories Inc.* (1:07-cv-00574).

RESPONSE TO REQUEST NO. 32:

Sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis objects to this request to the extent that it seeks documents and things outside sanofi-aventis’s possession, custody or control and specifically objects to the extent that it seeks information, documents or things that are in the possession, custody or control of Jagotec AG. Sanofi-aventis objects to this request to the extent that it seeks disclosure of third-party, confidential information. Sanofi-aventis also objects to this request as

irrelevant and overbroad to the extent it seeks documents and things concerning products other than those described by ANDA 79-013.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control that are located after a reasonable search provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 33:

All documents that have been disclosed or provided to any individual by, any scientist and/or consultant retained by Plaintiff in connection with the above-captioned action.

RESPONSE TO REQUEST NO. 33:

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term "scientist."

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, that have been disclosed or provided to any testifying experts in accordance with the Scheduling Order set by the Court provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 34:

All documents relating to any investigation or test conducted by any scientist and/or consultant retained by Plaintiff in the above-captioned action.

RESPONSE TO REQUEST NO. 34:

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as vague, ambiguous and uncertain, particularly with respect to the undefined term “scientist.”

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order,

sanofi-aventis will produce responsive, non-privileged documents within its possession, custody or control, located after a reasonable search, that have been disclosed or provided to any testifying experts in accordance with the Scheduling Order set by the Court provided this request is not rendered moot by any of the currently pending motions.

REQUEST NO. 35:

All documents that Plaintiff may use as an exhibit in any trial, hearing, submission to the court or deposition in the above-captioned action.

RESPONSE TO REQUEST NO. 35:

Sanofi-aventis objects to this request as premature given the current stage of this litigation. Furthermore, sanofi-aventis objects to this request as premature and untimely given the motions currently pending in front of this Court, the Judicial Panel on Multidistrict Litigation and the United States District Court for the District of Delaware as any or all of those motions may render this request moot. Sanofi-aventis also objects to this request as overly broad, unduly burdensome and calling for the production of documents and things that are neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Sanofi-aventis objects to this request to the extent that it calls for the production of documents and things that are protected from discovery by the attorney-client privilege, work-product doctrine or other applicable immunity. Sanofi-aventis further objects to this request as calling for the production of documents and things that are publicly available and/or already in the custody of Apotex and therefore are of no greater burden for Defendants to obtain than for Plaintiffs to obtain and produce.

Subject to these objections and its General Objections, following the resolution of each of the currently pending motions and entry of an appropriate agreed upon Protective Order, sanofi-aventis will identify documents it intends to use as exhibits: at hearing or trial in

accordance with the Scheduling Order set by the Court; in submissions to the Court when such submissions are made; and at depositions when such exhibits are formally marked as exhibits provided this request is not rendered moot by any of the currently pending motions.

Dated: February 19, 2008



Alfred J. Saikali (Fla. Bar No.: 178195)
asaikali@shb.com
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201 South Biscayne Boulevard - Suite 2400
Miami, Florida 33131-4332
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and

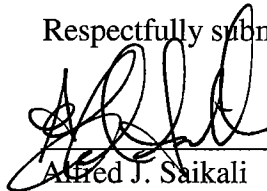
John M. Desmarais (jdesmarais@kirkland.com)
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New York, NY 10022-4611
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Fax: (212) 446-4900

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was faxed and served by U.S. mail this 19th day of February, 2008 to **Stephen J. Bronis, Esq., Jennifer Coberly, Esq.**, Zuckerman Spaeder LLP, 201 South Biscayne Boulevard, Suite 900, Miami, FL 33131; and **Robert B. Breisblatt, Esq.**, Welsh & Katz, Ltd., 120 South Riverside Plaza, Chicago, IL 60606.

Respectfully submitted,



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*Attorneys for Plaintiffs Sanofi-Aventis and
Sanofi-Aventis U.S. LLC*

EXHIBIT Z

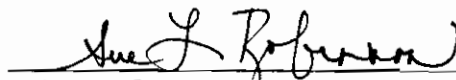
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CELGENE CORPORATION, NOVARTIS)	
PHARMACEUTICALS CORPORATION and)	
NOVARTIS PHARMA AG,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 06-741-SLR
)	
ABRIKA PHARMACEUTICALS, INC. and)	
ABRIKA PHARMACEUTICALS, LLLP,)	
)	
Defendants.)	

ORDER

At Wilmington this 18th day of July, 2007, having considered plaintiffs' motion for a voluntary dismissal without prejudice, and the papers submitted in connection therewith;

IT IS ORDERED that said motion (D.I. 57) is granted, as the court is not persuaded that the facts of this case warrant an exception to the "first filed rule."¹


United States District Judge

¹Although certainly the facts of this case would justify a healthy degree of cynicism regarding plaintiffs' motivation if they oppose an expeditious schedule in the New Jersey case.

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDPOINTE HEALTHCARE INC.,	:	
	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 07-4017 (JAP)
v.	:	
	:	
COBALT PHARMACEUTICALS INC.,	:	
	:	ORDER
	:	
Defendant.	:	
	:	

Presently before the Court is Defendant, Cobalt Pharmaceuticals Inc.’s (“Defendant”) motion to transfer or, in the alternative, stay these proceedings. Plaintiff, Medpointe Healthcare Inc. (“Plaintiff”) opposes the motion.

Both parties operate in the pharmaceutical industry. Plaintiff, a corporation headquartered in New Jersey, owns a patent for a prescription drug, Astelin®, that is used for the treatment of seasonal allergic rhinitis. The named inventor of Astelin® is located in Germany. The Defendant is a business incorporated and located in Canada. The Defendant prepared and compiled an abbreviated new drug application (“ANDA”) in Canada, which it filed with the United States Food and Drug Administration (“FDA”) seeking approval for the marketing of a generic drug to compete with Astelin®.

On August 22, 2007, Plaintiff filed an action alleging patent infringement in the District of New Jersey. Prior to Plaintiff filing this action, Plaintiff inquired as to whether the Defendant would consent to personal jurisdiction in New Jersey, which the Defendant refused to do. The

following day, on August 23, 2007, Plaintiff then filed an identical action in the Northern District of Illinois. The Defendant did not answer the complaint filed in New Jersey, but did answer and file a counterclaim in Illinois. On November 12, 2007, the Defendant filed the present action. The Court heard oral argument on January 25, 2008. Having reviewed the parties' submissions and considered their arguments, the Court now decides the matter.

Section 1404, subsection (a) of Title 28 in the United States Code provides "for the convenience of parties and witnesses, and in the interest of justice, a district court may transfer any civil action to any other district or division or where it might have been brought." The movant carries the burden of establishing the need for a transfer. *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995). In doing so, the movant must show that the alternative forum is not only adequate, but a more appropriate venue than the present forum. *Id.*

The Third Circuit in *Jumara* identified a number of factors a court should consider when determining whether a matter should proceed in another forum. Among these factors, a court should consider the parties' preference, where the claim arose, the convenience of the parties and witnesses, the location of books and records, public policy, and other practical considerations. *Id.* at 879-80.

Upon consideration of the various *Jumara* factors articulated in light of the present action, the Court finds that the action is appropriate to be litigated here. The location of Plaintiff's witnesses are in New Jersey. The Plaintiff is headquartered in New Jersey. Furthermore, the Defendant does not have any more connection with Illinois than it does with New Jersey and has not met its burden of demonstrating why the Northern District of Illinois is a more appropriate venue. Moreover, the Defendant represented that it would not contest personal jurisdiction in New Jersey and conceded that venue here is proper. Accordingly, **IT IS**

ON THIS 28th day of January, 2008,

ORDERED that Defendant's motion to transfer is **DENIED**.

/s/ JOEL A. PISANO
United States District Judge

EXHIBIT AA

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

FILED by _____	D.C.
APPEAL	
JUL 28 2000	
CLARENCE MADDOX CLERK U.S. DIST. CT. S.D. OF FLA. - MIAMI	

ABBOTT LABORATORIES,

CASE 00-6520-CV-SH

PLAINTIFF,

VS.

MIAMI, FLORIDA

JULY 10, 2000

ANDRX CORPORATION, ET AL.,

DEFENDANTS.

TRANSCRIPT OF SCHEDULING CONFERENCE
BEFORE THE HONORABLE SHELBY HIGHSMITH,
UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFF:

JOHN F. O'SULLIVAN, ESQ.
JAMES R. DALY, ESQ.
DAVID C. GOODWIN, ESQ.
AKERMAN & SENTERFITT
1 S.E. THIRD AVENUE, 28TH FLOOR
MIAMI, FL 33131 - 305/374-5600

FOR THE DEFENDANTS:

ERIC D. ISICOFF, ESQ.
MARTIN ENDRES, ESQ.
HERSCHEL SPARKS, ESQ.
ISICOFF & RAGATZ
1101 BRICKELL AVENUE, SUITE S-800
MIAMI, FL 33131 - 305/373-3232

REPORTED BY:

RANDALL J. BELSVIK, RPR
OFFICIAL COURT REPORTER
99 N.E. 4TH STREET, SUITE 1027
MIAMI, FL 33131 305-523-5178

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<u>DESCRIPTION</u>	<u>PAGE</u> <u>LINE</u>	<u>PAGE</u> <u>LINE</u>

CITATION TABLE

<u>CITATION</u>	<u>PAGE</u>	<u>LINE</u>
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1 MORNING SESSION

2 9:00 O'CLOCK A.M.

3 [CALL TO ORDER]

4 THE COURT: GOOD MORNING. PLEASE BE SEATED. ALL
5 RIGHT.

6 THE CLERK: ABBOTT LABORATORIES VERSUS ANDRX
7 CORPORATION, ANDRX PHARMACEUTICALS, INC. AND ANDRX
8 PHARMACEUTICALS L.L.C.

9 CIVIL CASE NUMBER 00-6520-CIVIL-HIGHSMITH. WOULD
10 COUNSEL FOR THE RESPECTIVE PARTIES PLEASE ANNOUNCE
11 THEMSELVES.

12 MR. GOODWIN: FOR PLAINTIFF ABBOTT LABORATORIES,
13 DAVID C. GOODWIN.

14 THE COURT: MR. GOODWIN.

15 MR. DALY: GOOD MORNING, YOUR HONOR. JAMES R.
16 DALY FOR JONES-DALY IN CHICAGO FOR THE PLAINTIFF ABBOTT
17 LABORATORIES.

18 THE COURT: MR. DALY.

19 MR. O'SULLIVAN: YOUR HONOR, JOHN O'SULLIVAN FROM
20 AKERMAN & SENTERFITT ALSO FOR ABBOTT LABORATORIES.

21 THE COURT: MR. O'SULLIVAN.

22 MR. ISICOFF: GOOD MORNING. ERIC ISICOFF FROM
23 MIAMI FOR THE ANDRX DEFENDANTS.

24 THE COURT: ALL RIGHT. MR. ISICOFF.

25 MR. ISICOFF: PRESENT WITH ME ARE MARTIN ENDRES

07/10/00

1 AND THIS IS HERSCHEL SPARKS, IN-HOUSE COUNSEL FOR THE
2 ANDRX.

3 THE COURT: WELL, WELCOME TO ALL OF YOU. MY
4 GOODNESS. HOW LONG HAS IT BEEN SINCE YOU HAVE BEEN IN MY
5 COURTROOM, DAVE GOODWIN?

6 MR. GOODWIN: JUDGE HIGHSMITH, PROBABLY NEVER IN
7 THIS COURTROOM.

8 THE COURT: THAT'S WHAT I WAS TRYING TO REFLECT
9 UPON. I KNOW I HAVE SEEN YOU ON OCCASION.

10 MR. GOODWIN: I THINK I HAVE SEEN YOU IN
11 CHAMBERS, AND THAT'S BEEN IN --

12 THE COURT: WELL, IT IS A DELIGHT, AS IT IS ALL
13 OF YOU. MR. GOODWIN AND I GO A LONG WAYS. WE WERE NEVER
14 TOGETHER PRACTICING AND WHATNOT. MOST OFTEN, SOMETIMES
15 OPPOSITE.

16 IN ANY EVENT, LET ME FIRST ADVISE YOU THAT I HOLD
17 THESE STATUS CONFERENCES IN ALL OF MY CIVIL CASES IN AN
18 EFFORT TO HOPEFULLY GET THEM STARTED ON THE RIGHT TRACK.

19 ORDINARILY, FOLLOWING A CONFERENCE OF THIS NATURE
20 -- THE STATUS CONFERENCE, IF YOU WILL -- THERE WOULD BE A
21 VERY COMPREHENSIVE ORDER THAT WOULD FOLLOW THAT WOULD SET
22 FORTH THE MATTERS THAT YOU MUST ACCOMPLISH, YOU AND YOUR
23 CLIENTS, IN THE INTERIM PRECEDING OF THE ULTIMATE TRIAL.

24 I DO NOT SET PRETRIAL CONFERENCES, EXCEPT IN VERY
25 UNUSUAL CIRCUMSTANCES. I FOUND THAT RELIANCE UPON THE

1 PRETRIAL CONFERENCE CONCEPT OFTEN LEADS THE COURT -- AS
2 WELL AS COUNSEL, ON OCCASION -- TO SORT OF IGNORE THE CASE
3 UNTIL THE PRETRIAL CONFERENCE, AND THEN WE ARE SET ON THE
4 TIME OF TRIAL OR ON THE EVE OF TRIAL.

5 IN ANY EVENT, ALL OF THE MATTERS THAT WOULD
6 OTHERWISE BE COVERED ON A PRETRIAL CONFERENCE WOULD
7 ORDINARILY BE COVERED NOT ONLY IN THIS CONFERENCE BUT IN
8 THE ORDER THAT WILL FOLLOW.

9 THIS IS A RATHER PECULIAR SITUATION. IT IS
10 OBVIOUSLY COMPLEX, WHAT WE WOULD PUT ON OUR COMPLEX TRACK,
11 BUT I AM TALKING ABOUT THE TWO OTHER PENDING PREVIOUSLY
12 FILED CASES IN OTHER JURISDICTIONS.

13 NOW, THERE HAS BEEN A MOTION TO STAY. WHAT IS
14 THE FEELING OF COUNSEL IN THAT REGARD? LET'S START WITH
15 YOU, MR. GOODWIN.

16 MR. GOODWIN: MAY I APPROACH THE LECTERN, YOUR
17 HONOR?

18 THE COURT: YES, PLEASE.

19 MR. GOODWIN: JUDGE, THE MOTION TO STAY, IF WE
20 COULD HOLD THAT BACK JUST FOR A HOUSEKEEPING MATTER FIRST,
21 PRO HAC PAPERS HAVE BEEN FILED ON BEHALF OF MR. JAMES R.
22 DALY. HE IS A MEMBER OF THE TRIAL BAR OF THE NORTHERN
23 DISTRICT OF ILLINOIS. HE IS HERE WITH US THIS MORNING.
24 OBVIOUSLY, WE WOULD WANT HIM APPROVED.

25 THE COURT: ALL RIGHT.

1 MR. ISICOFF: NO OBJECTION, YOUR HONOR.

2 THE COURT: VERY WELL. CERTAINLY. WELCOME.

3 MR. DALY: THANK YOU, YOUR HONOR.

4 MR. GOODWIN: ON THE MOTION TO STAY, YOUR HONOR,
5 AND I WAS GOING TO BE TALKING MORE IN TERMS OF THE
6 SCHEDULING CONFERENCE AND SOME OF THE DATES -- AND WE HAVE
7 MET, WE HAVE DONE OUR RESPECTIVE HOMEWORKS, WE HAVE DONE
8 ALL THAT, BUT ON THE FACTUAL MATTERS CONTAINED, AS YOUR
9 HONOR KNOWS, AND THE MEMORANDUM IN SUPPORT THAT WAS FILED
10 UNDER SEAL -- AND SO THAT I DON'T MISSTEP OR SAY SOMETHING
11 BECAUSE I AM NEWLY ACTIVATED INTO THIS MATTER, WOULD IT BE
12 ALL RIGHT IF MR. DALY CAME HERE AND ADDRESSED THESE MOTIONS
13 TO STAY?

14 THE COURT: OF COURSE. MR. DALY?

15 MR. DALY: THANK YOU, YOUR HONOR. YOUR HONOR,
16 THE -- BY WAY OF BACKGROUND TO THE MOTION TO STAY, THE
17 REASON THAT WE HAVE THESE THREE PARALLEL LAWSUITS GOING ON
18 AT THE SAME TIME IS AS FOLLOWS:

19 WHEN ABBOTT RECEIVED THE NOTICE, THE PARAGRAPH
20 HAD CERTIFICATION FROM ANDRX. WE HAD 45 DAYS WITHIN WHICH
21 TO BRING AN ACTION AGAINST THE DEFENDANTS.

22 WHEN WE GOT THE NOTICE, THE NOTICE THAT HAD BEEN
23 FILED BY ANDRX L.L.C., AND WE TOOK A LOOK AT IT AND STARTED
24 TO DO SOME RESEARCH ON WHO ANDRX L.L.C. WAS, WE FOUND OUT
25 THAT THEY WERE A NEWLY FORMED LIMITED LIABILITY COMPANY IN

1 VIRGINIA. WE LOOKED AT THE PARENTS. WE FOUND OUT THAT
2 THEY HAD JUST BEEN FORMED A COUPLE OF WEEKS EARLIER. AND
3 WE BELIEVE THAT WE HAD A BASIS FOR JURISDICTION OVER ALL
4 THREE DEFENDANTS IN CHICAGO.

5 SO WE FILED FIRST THERE AND WAITED TO SEE WHAT
6 THE DEFENDANTS DID WITH RESPECT TO THE ISSUE OF PERSONAL
7 JURISDICTION.

8 AS ANTICIPATED, ALL THREE DEFENDANTS CAME INTO
9 CHICAGO AND CONTESTED THE ISSUE OF PERSONAL JURISDICTION.
10 WE THEN MOVED THE COURT FOR EXPEDITED DISCOVERY, GOT IT,
11 GOT ALL THE BRIEFING DONE, BUT WE WERE UNABLE TO GET A
12 DECISION OUT OF THE NORTHERN DISTRICT OF ILLINOIS WITHIN
13 THE INITIAL 45 DAYS.

14 AND THE IMPORTANCE OF THAT IS, IS THAT IF YOU
15 DON'T HAVE AN ACTION PENDING AGAINST THE DEFENDANTS WITHIN
16 THAT 45 DAYS, YOU LOSE THE THREE-MONTH STAY THAT IS
17 STATUTORILY PROVIDED FOR PROHIBITING FINAL F.D.A. APPROVAL
18 OF THE END.

19 SO UNDER THE THEORY THAT WITH THE IMPORTANCE OF
20 THAT ISSUE, 99.9 PERCENT SURETY EVEN WOULD NOT BE ENOUGH,
21 WE WENT AHEAD AND WE SUED ALL THREE DEFENDANTS HERE IN
22 FLORIDA, WHICH IS WHERE THE ANDRX CORPORATION AND ANDRX
23 PHARMACEUTICAL, INC. ARE LOCATED, AND WE ALSO SUED THE
24 L.L.C., HERE ON THE BASIS THAT ALL OF THE ACTS THAT IT
25 APPEARS TO HAVE DONE -- IN OTHER WORDS, THE SENDING OF THE

1 NOTICE, THE FILING WITH THE F.D.A. -- APPEARS TO HAVE
2 EMANATED UNDER FLORIDA FOR ALL THREE DEFENDANTS.

3 AND THEN NOT KNOWING WHAT THE L.L.C. WOULD DO,
4 WHETHER THEY WOULD EVEN CONSENT TO JURISDICTION HERE, WE
5 ALSO SUED THE L.L.C. ALONE IN VIRGINIA JUST TO MAKE SURE
6 THAT WE HAD A LAWSUIT ON FILE WITHIN THE 45 DAYS.

7 IN TERMS OF THIS COURT, THE L.L.C. HAS RAISED
8 PERMANENT JURISDICTION AS AN AFFIRMATIVE DEFENSE HERE, SO
9 WE ARE NOT 100 PERCENT SURE WHERE WE ARE GOING TO END UP.
10 I CAN TELL THE COURT AND COUNSEL, WE TALKED OUTSIDE BEFORE
11 COMING IN, WE HAVE BEEN INFORMED IN CHICAGO BY JUDGE HIBLER
12 THAT HE IS READY TO RULE. WE BELIEVE THE OPINION HAS BEEN
13 WRITTEN.

14 WHAT I DID LAST WEEK, YOUR HONOR, IS SEND OUT AN
15 ORDER INDICATING THAT HE WAS READY TO RULE; BUT BECAUSE THE
16 PARTIES HAD ENTERED INTO A PROTECTIVE ORDER AND FILED THE
17 BRIEFS UNDER SEAL, HE WANTED PUBLIC BRIEFS TO BE FILED WITH
18 THINGS REDACTED IF WE COULD NOT AGREE SO HE WOULD KNOW
19 EXACTLY WHAT HE COULD AND COULD NOT SITE FACTUALLY IN HIS
20 PAPER IN ACCORDANCE WITH THE PROTECTIVE ORDER.

21 THAT HAS BEEN ACCOMPLISHED BY THE PARTIES IN
22 CHICAGO LAST WEEK AND WE ARE EXPECTING A RULING OUT OF THE
23 COURT ANY DAY.

24 IN VIRGINIA, YOUR HONOR, WE MOVED FOR A STAY AND
25 WE ARGUED THAT -- I THINK IT WAS ON JUNE 7, AND THE COURT

1 IN VIRGINIA HAS ISSUED A STAY PENDING RESOLUTION OF THE
2 MOTION THAT STANDS BEFORE JUDGE HIBLER IN THE NORTHERN
3 DISTRICT OF ILLINOIS.

4 THE ISSUE THAT THE COURT THERE IS FACING -- NOT
5 TO GO INTO TOO MUCH DETAIL -- IS THAT THERE IS A BODY OF
6 CASE LAW THAT TALKS ABOUT PIERCING THROUGH THE PARENTS TO
7 GET TO THE SON TO BRING THE DEFENDANTS TO COURT IN A
8 JURISDICTION WHERE THE PARENTS ARE SUBJECT TO SUIT.

9 AND WE, ANDRX PHARMACEUTICAL, INC., DOES BUSINESS
10 IN ILLINOIS. THAT IS SOMETHING THAT WE WERE ABLE TO
11 ESTABLISH UNDER OUR EXPEDITED DISCOVERY THERE.

12 AND WE BELIEVE THAT THE CREATION OF THE L.L.C.
13 FOR THE SOLE PURPOSE OF ATTEMPTING TO FORCE PLAINTIFFS TO
14 SUE THE DEFENDANTS ONLY IN THE NORTHERN -- OR IN THE
15 DISTRICT OF VIRGINIA IS NOT GOING TO SUCCEED, WE BELIEVE,
16 AND WE HAVE FOUND GOOD AUTHORITY TO THAT EFFECT, INCLUDING
17 SOME CASES THAT SAY THAT TAKING PATENTS AND ASSIGNING THEM
18 TO A SUB THAT NEVER GOES OUTSIDE A GIVEN JURISDICTION IS
19 NOT GOING TO BE A BAR TO THE PLAINTIFFS BEING ABLE TO SUE
20 THE REAL PARTIES IN INTEREST.

21 SO WE HAVE SIMPLY BROUGHT THAT MATTER IN OUR
22 MOTION TO THE COURT'S ATTENTION HERE. I WANTED TO TAKE THE
23 OPPORTUNITY TO EXPLAIN WHY WE HAVE THREE LAWSUITS PENDING.
24 IT IS OUR HOPE THAT THE COURT IN ILLINOIS DENIES THE MOTION
25 TO DISMISS, IN WHICH CASE WE WOULD BE ASKING THE COURT IN

1 VIRGINIA AND THIS COURT TO TRANSFER THESE ACTIONS TO THE
2 DISTRICT OF ILLINOIS WHERE -- WHICH IS THE FIRST FILED
3 ACTION.

4 AND IF THE COURT IN CHICAGO WERE TO DENY -- OR TO
5 GRANT THE MOTION TO DISMISS, YOUR HONOR, WE WOULD THEN ASK
6 THIS COURT AND THE COURT IN VIRGINIA TO TRANSFER THE ACTION
7 TO THIS COURT, WHICH IS A COURT WHERE ALL THREE DEFENDANTS
8 HAVE NOW APPEARED AND ANSWERED.

9 AND SO -- AND AGAIN, IN TERMS OF THE TIME THAT WE
10 ARE LOOKING AT, JUDGE, ALL INDICATIONS APPEAR TO BE THAT IT
11 SHOULD BE WITHIN A WEEK OR WITHIN A COUPLE OF WEEKS GIVEN
12 THE ADVICE THAT WE HAVE RECEIVED FROM CHAMBERS IN CHICAGO.

13 THE COURT: MR. ISICOFF?

14 MR. ISICOFF: THANK YOU, YOUR HONOR. YOUR HONOR,
15 OUR POSITION IS AS FOLLOWS: WE CERTAINLY UNDERSTAND THAT
16 IF THE COURT IN ILLINOIS IS GOING TO RULE WITHIN THE NEXT
17 FEW DAYS, A WEEK OR SO, IT MAY WELL MAKES SENSE TO WAIT FOR
18 THAT PERIOD OF TIME.

19 HOWEVER, WE DO BELIEVE THAT VENUE JURISDICTION IS
20 MOST APPROPRIATE HERE. WE HAVE ANSWERED -- WE ARE PREPARED
21 TO GO FORWARD. THE 30 MONTH AUTOMATIC STAY THAT MR. DALY
22 MENTIONED IS EXACTLY THE REASON WHY IT IS VERY IMPORTANT
23 THAT WE DO NOT DELAY.

24 AS THIS COURT KNOWS, THE MERE FILING OF THIS
25 ACTION THROWS INTO EFFECT A THREE MONTH STAY WHICH CAN BE

1 ONLY DENIED BY THE CONCLUSION OF THIS ACTION. SO IT IS
2 VERY IMPORTANT FOR US TO MOVE QUICKLY AS FAR AS WE CAN AND
3 THAT IS WHY WE HAVE COME INTO COURT.

4 WE ARE TRYING TO MOVE THIS CASE FORWARD. AS THE
5 COURT HAS SEEN, THE DISCOVERY DATES AS SUGGESTED -- WE
6 WOULD LIKE TO PUT A REASONABLE TIME TO DISCOVERY AND OTHER
7 TRIAL MATTERS AND TRY TO GET THIS CASE TRIED WITHIN A
8 REASONABLE PERIOD OF TIME.

9 IF, FOR EXAMPLE, THE COURT IN ILLINOIS DOES NOT
10 RULE, IF THE INFORMATION WE HAVE ISN'T ACCURATE OR IF THE
11 COURT HAS SOME DIFFICULTY WITH SOME ASPECT OF THE OPINION
12 IT IS WRITING, IT COULD BE MONTHS, THREE MONTHS, FOUR
13 MONTHS, FIVE MONTHS THAT THERE IS A DELAY IN THAT DECISION,
14 THAT, OF COURSE, WOULD HAVE A TREMENDOUS IMPACT ON US HERE
15 BECAUSE WE ARE READY AND PREPARED TO GO FORWARD.

16 REALISTICALLY, THE CASE IN VIRGINIA IS NOT GOING
17 TO GO FORWARD -- IF THE COURT IN ILLINOIS DENIES IT TO GO
18 FORWARD, THEN WE GO THERE. IF THE COURT GOES AHEAD AND
19 CONCLUDES THERE IS NO JURISDICTION THERE, THEN WE GO HERE.

20 SO IT IS VERY CLEAR THAT WAITING AROUND IS
21 PROBABLY NOT IN ANYBODY'S INTEREST, CERTAINLY NOT IN
22 ANDRX'S INTEREST. AND THIS CASE WILL LITERALLY LANGUISH
23 AND BE IN A STAMPED PATTERN FOR A CONSIDERABLE PERIOD OF
24 TIME UNLESS THE COURT IN ILLINOIS RULES.

25 SO WE WOULD SUGGEST THAT IF THE COURT IS INCLINED

1 TO WAIT, THAT WE PUT A VERY, VERY SHORT TIME FRAME HERE SO
2 WE DON'T GET CAUGHT IN A SITUATION WHERE A DELAYED RULING
3 COULD LITERALLY STOP THIS CASE COLD IN ALL COURTS FOR A
4 CONSIDERABLE PERIOD OF TIME, AND TIME IS OF THE ESSENCE IN
5 THIS TYPE OF LITIGATION.

6 THE COURT: THANK YOU, MR. ISICOFF. WELL, FIRST
7 OF ALL, I DO NOT KNOW -- WHO WAS THE JUDGE IN THE NORTHERN
8 DISTRICT OF ILLINOIS?

9 MR. ISICOFF: JUDGE HIBLER, I BELIEVE.

10 MR. DALY: YES. WILLIAM HIBLER, YOUR HONOR.

11 THE COURT: HIBLER?

12 MR. DALY: YES.

13 THE COURT: I HAVE A FEELING THAT HE IS PREPARED
14 TO RULE. I ABHOR UNUSUAL DELAY IN THIS COURT. AND MOST OF
15 MY COLLEAGUES FEEL THE SAME WAY. WE SOMETIMES GET A LITTLE
16 BIT IMPATIENT WITH OUR OWN CIRCUIT COURT, BECAUSE IT SEEMS
17 ON OCCASION TO TAKE THEM MUCH LONGER TO ALREADY MAKE UP
18 THEIR MINDS, ALBEIT THEY MUST EITHER AGREE OR AGREE TO
19 DISAGREE.

20 IN ANY EVENT, LET ME ASSURE YOU, FIRST OF ALL, I
21 AM GOING TO GRANT THE MOTION TO STAY. I AM GOING TO STAY
22 THIS WILL MATTER FOR 30 DAYS APPROXIMATELY. LET'S SEE.

23 [PAUSE]

24 YES. RESET THIS HEARING -- IF HE HAS DENIED THE
25 MOTION OR IF HE HAS GRANTED IT -- ALL RIGHT, SO THAT I CAN

1 TALK WITH COUNSEL ABOUT PRECISELY WHAT THEIR NEXT
2 DISCLOSABLE MOVES ARE, IF YOU WILL.

3 LET ME ALSO ASSURE YOU THAT THIS DELAY WILL NOT
4 IN MY OPINION OPERATE TO THE PREJUDICE OF ANYONE FOR THE
5 SIMPLE REASON THAT WE HAVE MADE, I BELIEVE, GREAT STRIDES
6 IN THE NINE YEARS OR SO THAT I HAVE NOW BEEN ON THIS BENCH
7 IN MOVING OUR CIVIL CALENDARS.

8 WHEN I CAME ON THIS BENCH IN 1991, THE ROUTINE
9 TIME PERIOD BEFORE A CIVIL CASE OF ANY KIND COULD GET TO
10 TRIAL WAS THREE YEARS. MY CASES NOW PROCEED TO TRIAL
11 WITHIN A YEAR FROM CONFERENCE, AND THAT IS BECAUSE I HOLD
12 THE PARTIES TO THE DEADLINES SET IN THE ORDER THAT I WILL
13 ISSUE.

14 NOW, I SAID 30 DAYS. IT MIGHT BE 29 OR 31 OR 26,
15 SOMETHING OF THAT NATURE, DEPENDING UPON WHETHER IT FALLS
16 ON A WEEKEND OR ON A DAY THAT I WOULD OTHERWISE BE
17 UNAVAILABLE. SO IT WILL BE WITHIN THAT FRAME WORK, WITHIN
18 THOSE PARAMETERS.

19 AND IF THE MOTION IS GRANTED, MOTION TO DISMISS,
20 YOU MAY ANTICIPATE WE WILL BE READY FOR THE FINAL STATUS
21 CONFERENCE. ALL RIGHT.

22 IT IS AN INTERESTING QUESTION. UNFORTUNATELY --
23 I SAY "UNFORTUNATELY" -- FOR THIS COURT THERE MAY BE MANY
24 SIMILAR CASES. SO PROBABLY THE SOONER THIS PARTICULAR
25 ASPECT OF CASE, IF YOU WILL, IS ADDRESSED, THE

1 BETTER, BECAUSE AT LEAST THERE WILL BE A PRECEDENT. VERY
2 WELL. IS THERE ANYTHING ELSE WE CAN TALK ABOUT TODAY?

3 MR. ISICOFF: NO, YOUR HONOR.

4 MR. GOODWIN: NO.

5 THE COURT: ALL RIGHT. THANK YOU VERY MUCH FOR
6 YOUR APPEARANCE AND YOUR REPORT. I WISH YOU WELL. HAVE A
7 NICE DAY.

8 [PROCEEDINGS CONCLUDED]

9 C E R T I F I C A T E

10 I HEREBY CERTIFY THAT THE FOREGOING IS AN ACCURATE
11 TRANSCRIPTION OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

12
13 7/17/00
14 DATE FILED

15 Randall J. Belvik
16 RANDALL J. BELSVIK, RPR
17 OFFICIAL COURT REPORTER
18 99 N.E. 4TH STREET, SUITE 1027
19 MIAMI, FL 33131 305-523-5178
20
21
22
23
24
25

EXHIBIT BB

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION**

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

**PLAINTIFFS' MOTION FOR STATUS CONFERENCE
AND INCORPORATED MEMORANDUM OF LAW**

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") respectfully request a brief status conference with the Court to discuss the present state of the litigation. Specifically, sanofi-aventis seeks to address (1) the status of the related Delaware actions, in which the Delaware court has scheduled its Rule 16 conference with all parties for March 17, 2008; (2) the transfer motions currently pending before the Court, the Delaware court, and the Judicial Panel on Multidistrict Litigation ("the Panel"), and the impact of these motions on the present litigation; (3) the necessity and timing of a Markman hearing and dispositive motions; and (4) discovery limitations and scheduling. A status conference to address these outstanding issues concerning venue, discovery and scheduling is necessary at this time because their resolution will directly and immediately effect the parties' conduct in, and the Court's management of, the litigation.

Pursuant to S.D. Fla. L.R. 7.1.A.3(a), Plaintiffs' counsel conferred with Defendants' counsel in a good faith effort to resolve the issues raised by this Motion. No resolution was obtained.

WHEREFORE, Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC respectfully request that the Court enter an Order granting Plaintiffs' Motion for Status Conference.

MEMORANDUM OF LAW

This case is a second-filed action based on Apotex Corp. and Apotex Inc.'s (collectively "Apotex") infringement of United States Patent No. 4,661,491 ("the '491 patent") by filing an Abbreviated New Drug Application ("ANDA") seeking FDA approval to manufacture, sell and use a generic version of sanofi-aventis's drug Uroxatral®. A parallel first-filed action, involving the same claims, defenses and counterclaims, is pending against Apotex in the district of Delaware. Two related actions are also pending in Delaware against 13 other defendants for infringement the '491 patent and/or United States Patent No. 6,149,940, both listed in the FDA Orange Book for sanofi-aventis U.S. LLC's drug Uroxatral® and to which sanofi-aventis is an assignee. The Delaware court has scheduled a Rule 16 status and scheduling conference for all three actions on March 17, 2008. Ex. 1, February 26, 2008 Rule 16 Orders in *Sanofi-aventis et al. v. Apotex Inc. et al.*, No.07-792 (GMS) (MPT), *Sanofi-aventis et al. v. Actavis South Atlantic LLC et al.*, No. 07-572 (GMS) (MPT) and *Sanofi-aventis et al. v. Barr Laboratories, Inc.*, No. 07-574 (GMS) (MPT).¹

The pleading stage of this action is complete, and the Court issued scheduling orders on January 3 and 22, 2008 setting various dates including mediation (April 28, 2008), final discovery cut-off (August 6, 2008) and trial (two weeks starting October 6, 2008). D.I. 4; D.I.

¹ A true and accurate copy of Exhibit 1 is attached to the accompanying Declaration of Alexis Gorton In Support of Plaintiffs' Motion for Status Conference.

23. The Court has not, however, scheduled other pretrial activities, such as a Markman hearing for claim construction, or set limitations on discovery, such as on the number of depositions each party may take and the number of document requests, interrogatories, and requests for admission that each party may serve. Additionally, the following motions are currently pending before the Court: Plaintiffs' Motion to Stay or Transfer (D.I. 5), Plaintiff's Motion for a Protective Order (D.I. 44), Plaintiff's Motion to Compel Defendants to Comply With The Court's February 20, 2008 Order (D.I. 54). Also currently pending in the Delaware court is Apotex's Motion to Transfer, or in The Alternative, to Stay, and at the Panel is sanofi-aventis's Motion to Transfer and Consolidate for Pretrial Proceedings. To date, the Court has not held an initial case management conference in this action.

Sanofi-aventis respectfully requests that the Court schedule a brief status conference to address the issues outlined above as they will directly and immediately impact the parties' conduct in, and the Court's management of, the litigation. As an initial matter, it is within the Court's discretion to schedule a status conference and parties may move the court to schedule such a conference. *See* 3-16 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE § 16.60 (Matthew Bender 3d ed.). Here, a status conference at this stage of the litigation would benefit both the parties and the Court. First, a conference would provide the parties with an opportunity to update the Court on the status of the three related actions currently pending in Delaware, including the identical, first-filed action against Apotex. Second, the parties and the Court can use the conference to address the various venue issues raised in the motions to transfer, stay, and/or consolidate pending before the Court, the Delaware court, and the Panel, and to address the impact of the venue issues on the parties' pretrial activities in this action. Third, at the conference, the parties can address the need for and timing of other pretrial activities such as

claim construction briefing and a Markman hearing, which are necessary for the Court to issue claim constructions that will govern the parties' infringement and invalidity positions in this case. Finally, a conference will allow the parties and the Court to outline a roadmap for the most efficient conduct of discovery in this matter, which sanofi-aventis expects to be wide-ranging based on its investigation and the discovery requests served by Apotex to date, by setting additional discovery deadlines as well as limitations on depositions, document requests, interrogatories, and requests for admission.

For the foregoing reasons, the Court should enter an Order granting Plaintiffs' Motion for Status Conference.

Dated: February 27, 2008

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 27, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

s/ Alfred J. Saikali

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Attorneys for Plaintiffs

SERVICE LIST

SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL

Case No.: 07-61800-CIV-Moreno/Simonton

**United States District Court
Southern District of Florida
(Miami Division)**

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,
Defendants.

/

**[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION FOR STATUS CONFERENCE**

THIS CAUSE is before the Court on Plaintiffs' Motion for Status Conference, filed on February 27, 2008, and having considered the Motion and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiffs' Motion for Status Conference is GRANTED.

A status conference will be held on _____, 2008, at _____.

DONE AND ORDERED in Chambers at _____, _____ County, Florida, this _____ day of February, 2008.

Honorable Federico A. Moreno
United States District Court Judge

EXHIBIT CC

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

**DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO TRANSFER OR STAY**

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") respectfully submit this memorandum in opposition to Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") Motion to Transfer or Stay and Supporting Memorandum of Law.

Litigation in this Florida action is now well underway. This Court already has set a discovery schedule with a discovery cut-off of August 6, 2008 and a trial date of **October 6, 2008**. See January 22, 2008 Order (Dkt. No. 23). The parties in Florida already have had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, and begun serving discovery. By contrast, other than initial pleadings, the Delaware action has not yet begun.

One of the primary purposes of the *Hatch-Waxman* Act is to expedite resolution of patent disputes involving drug products in order to facilitate the public's access to less expensive generic drugs. 21 USC §355(j)(5)(B)(iii) (parties required to "reasonably cooperate in expediting the action."); H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt. 1 at p. 28, *reprinted in*

1984 U.S.C.C.A.C. 2647. Allowing the case to remain in Florida will accomplish that goal. However, transferring this case to Delaware will needlessly slow the resolution of this matter.

Sanofi cannot satisfy its heavy burden of showing Delaware is the more convenient forum. In fact, all relevant factors indicate Florida is the much more convenient and logical forum for this action. One of the Defendants, Apotex Corporation, which will market and sell the allegedly infringing drug product, has its headquarters in Florida. *See* Declaration of Tammy McIntire, attached hereto as Exhibit A at ¶4. Sanofi has accused Apotex Corp. of aiding and abetting, inducing and contributing to the infringement of its patent. Fla. Compl. ¶15 (Dkt.1). While Apotex disputes these accusations (and does not believe they state a claim for infringement under 35 U.S.C. §271(e)(2)), the situs of these alleged acts, and any Apotex Corp. documents and witnesses, necessarily would be Florida.

None of the parties have active operations in Delaware. Apotex Corp.'s operations are located in Florida. Apotex, Inc., whose act of filing an abbreviated new drug application ("ANDA") to market a generic version of an approved drug is the alleged act of infringement under 35 U.S.C. §271(e)(2), is a Canadian company whose operations are based in Canada. *See* Declaration of Bernice Tao attached hereto as Exhibit B at ¶¶4, 6. Sanofi-Aventis U.S., who presently markets the drug at issue here, is located in New Jersey. Its parent, Sanofi-Aventis, which purports to own the patents in suit, is located in France. None of the acts accused of infringement here have any connection to Delaware. None of the documents necessary as evidence for this matter are located in Delaware. (Exhibit A at ¶7; Exhibit B at ¶9). None of the potential witnesses are located in Delaware. (Exhibit A at ¶ 6; Exhibit B at ¶8).

The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C., which courts have recognized is not a significant factor in the §1404

analysis – indeed state of incorporation is not listed in §1404 as a factor to consider in determining an appropriate forum. 28 U.S.C. §1404; *see also Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 77 F.Supp.2d 505, 509 n. 6 (D. Del. 1999) (“Although the court does not mean to suggest that a defendant’s state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive.”).

Sanofi’s reliance on the Delaware litigation having been filed mere days before this litigation is misplaced. The first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues.

Accordingly, the Court should refuse to transfer this litigation to Delaware and allow this matter to proceed at the expedited pace in Florida.

ARGUMENT

I. Sanofi’s Arguments Ignore that Proceeding In Florida Would Expedite Resolution Of This Action

As noted above, the Hatch-Waxman Act requires the parties to an ANDA action to cooperate with each other in expediting the resolution of the action. 21 USC § 355 (j)(5)(B)(iii) (“In such an action, each of the parties shall reasonably cooperate in expediting the action.”). Apotex requested that Sanofi agree to proceed in Florida based on the expedited trial date. Sanofi refused and filed its motion to transfer. The Court should enforce the intent of the Hatch-Waxman Act and allow this litigation to proceed in the most expeditious fashion, which means keeping this case in Florida. *See In re Barr Labs., Inc.* 930 F.2d 72, 76 (D.C. Cir. 1991) (noting Congress enacted the Hatch-Waxman Act to “get generic drugs into the hands of patients at reasonable prices – fast.”).

There can be no dispute that proceeding with this case in Florida will expedite this litigation. This Court has entered a Scheduling Order setting a discovery schedule and a trial

date in October 2008, and discovery already is underway in this case. *See* January 22, 2008 Order (Dkt. 23).

Sanofi's contention that the scope of discovery requires this matter to proceed on a slower track is now moot. As stated in Sanofi's motion for transfer at pg. 17, Sanofi requested the court to place this action on a complex track under Local rule 16.1.A. *See Plaintiffs' Motion to Continue Pretrial Deadlines and Trial and Supporting Memorandum of Law* (Dkt. 12). The Court was presented with Sanofi's arguments relating to the complex nature of this case and scope of discovery as well as Sanofi's request to extend the end of discovery an additional 13 months (April, 2009) and extending the trial date from May, 2008 to September, 2009. (Dkt. 12). The Court nevertheless granted only a short extension with the close of discovery in August, 2008, a dispositive motion deadline of August 20, 2008 and a trial date of October 6, 2008. (Dkt. 23).

Transferring this litigation to Delaware, as Sanofi suggests, where Sanofi has sued 13 other ANDA holders for the infringement of not only the '491 patent but also the '940 patent, will only slow the adjudication process. Although Sanofi has not yet sued Apotex for the infringement of the '940 patent, Apotex has counterclaimed seeking a declaration that its ANDA product does not infringe that patent because Apotex's proposed drug product is **different** from what is claimed in the '940 patent. In fact, it is likely that Apotex's ANDA product is substantially different (and therefore not infringing) from the other Delaware defendants, and that the Delaware litigation against Apotex – whether alone or in combination with other ANDA

holders – will not be in a position where discovery would be done less than seven months from now, and trial would occur less than nine months from now.¹

Because of these differences transfer to Delaware and consolidation on the infringement issues likely will cause delay, as the parties and the Court sort out the issues of competitive sensitivity and confidentiality amongst the other generic defendants and their competing ANDA products. All of this delay is avoided if the case remains here in Florida.

To be sure there may be overlap between the Delaware parties' invalidity arguments and those of Apotex. But the evidence and arguments raised also may be significantly different, as each party determines its strongest defenses. To the extent that the invalidity or other issues in the case overlap, the remaining Delaware cases will benefit from the work already done on those issues in Florida. And the rulings in Florida, while not binding, will surely be instructive and also will help to narrow if not resolve the issues remaining here to everyone's benefit.

II. All Relevant Factors Weigh Against Transfer To Delaware

The factors dictated by 28 U.S.C. §1404 also favor keeping this case in Florida. Specifically, §1404 requires the Court to consider the location of evidence, the convenience of the parties, the convenience of the witnesses and the interests of justice. Sanofi, as the moving party, has the burden of showing Delaware as the more appropriate venue under the factors. *Central Money Mortg. Co. v. Holman*, 122 F. Supp. 2d 1345, 1346 (M.D. Fla. 2000) (“[T]he movant has the burden of persuading the trial court that transfer of venue should be granted.”). The public and private interest factors considered are outlined in the Southern District of

¹ Although Apotex's ANDA product does not infringe Sanofi's '940 patent, because Sanofi listed the '940 patent in the Orange Book it remains a cloud over Apotex's ANDA product, and is delaying Apotex's ability to get to market. *See Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006). Accordingly, Apotex has counterclaimed against Sanofi seeking patent certainty and a judicial declaration that the '940 patent also is not infringed by its ANDA product. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007).

Florida's decision in *Jewelmasters, Inc. v. May Dep't Stores*, 840 F. Supp. 893, 895 (S.D. Fla. 1993):

The idea behind § 1404 (a) is that where a 'civil action' to vindicate a wrong -- however brought in a court -- presents issues and requires witnesses that make one District Court more convenient than another, the trial judge can, after findings, transfer the whole action to the more convenient court." *Continental Grain Co.*, 364 U.S. at 26. To determine the appropriateness of such a transfer, the Court must weigh a variety of factors, including (1) the convenience of the parties; (2) the convenience of the witnesses; (3) the relative ease of access to sources of proof; (4) the availability of process to the presence of unwilling witnesses; (5) the cost of obtaining the presence of the witnesses; and (6) the public interest.

Sanofi does not satisfy its burden by showing Delaware is a more convenient forum. Weighing the relevant interests renders Florida the more appropriate forum. With respect to the public's interest, the public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). The above-quoted sections of the Hatch-Waxman Act dealing with the parties' obligation to expedite resolution of this matter further dictate that Florida is the appropriate forum for this action.

Further, Sanofi's arguments concerning conservation of judicial resources through combining this action with the other cases pending in Delaware are illusory. Transferring a case set on a 9-month track to trial to a jurisdiction where it will be joined with 13 other cases involving a number of different infringement issues, and where no trial date has been set will not conserve judicial resources. The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C. Neither company has active

operations in Delaware. Apotex Corp.'s headquarters is located in Florida and Apotex, Inc. is located in Canada. Sanofi-Aventis U.S. is located in New Jersey and its parent, Sanofi-Aventis is located in France. Although the Defendants' state of incorporation is not irrelevant to a transfer inquiry, it certainly is not dispositive. *Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 77 F.Supp.2d 505, 509 FN 6 (D. Del. 1999) ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive."). In fact, a defendant's place of incorporation is not mentioned in §1404 or among the six factors outlined by the Southern District of Florida in considering a motion to transfer. *Jewelmasters, Inc.*, 840 F. Supp. at 895.

The operative facts giving rise to this litigation are centered in Florida, Canada, France, and New Jersey, *not* Delaware. 17 Moore's Federal Practice 3d, § 111.13(1)(d) at 111-71 ("If none of the operative events in the lawsuit took place in the district in which the action was originally filed, a motion to transfer to the district in which the events occurred is likely to succeed...."). None of the alleged infringing activities took place in Delaware. (Exhibit A at ¶ 6-8). The filing of the ANDA with Paragraph IV certification was the purported act of infringement prompting this litigation and was initiated from Canada. (Exhibit A at ¶ 5-7; Exhibit B at ¶ 6-9). None of the documents relevant to this litigation are in Delaware. (Exhibit A at ¶ 7; Exhibit B at ¶ 9). The ANDA filing, Paragraph IV Certification, and further correspondence with the FDA are the operative facts and documents relevant to this litigation, all of which originated from or are located in Canada or Florida.

The convenience of the witnesses also favors transfer to Florida. *Amersham Pharmacia Biotech v. Perkin-Elmer Corp.*, 11 F. Supp. 2d 729, 730 (S.D.N.Y. 1998) ("Evaluation of the first two factors [(1) the convenience of witnesses; (2) the location of relevant documents and

relative ease of access to sources of proof] is typically dependent, moreover, on identification of the fourth factor, the "locus of the operative facts."). All persons knowledgeable Apotex Corp.'s alleged acts of infringement are located in Florida. Accordingly, Florida is a more convenient and logical forum for this litigation.

Without any legitimate basis to support transferring this case to Delaware, Sanofi instead tries to shift the burden to Apotex to establish that the case should remain in Florida. For example, Sanofi attempts to compare this case to that of *Alcon Mfg., Ltd. v. Apotex Inc.*, No. 1:06-cv-1642-RLY-TAB, 2007 WL 854026 (S.D. Ind. Mar. 14, 2007), where Apotex filed a motion to transfer venue from the Southern District of Indiana to the Southern District of Florida. However, *Alcon*, is nothing like the present case – most significantly, Alcon (unlike Sanofi) did not sue Apotex in the Southern District of Florida. Further, in the *Alcon* case Apotex was the moving party and therefore had the burden of persuading the Indiana court to transfer the case away from the plaintiff's chosen forum. Here, Sanofi is the moving party and chose to sue Apotex here. Unlike the situation in *Alcon* the parties already have engaged in the litigation process and begun discovery in Florida. There has been no such progression in Delaware. In any event, Sanofi, not Apotex, carries the burden of establishing transfer is appropriate. It has failed to do so.

III. Plaintiffs Voluntarily Chose Florida As A Forum And The First-Filed Rule Does Not Apply

Sanofi chose Florida as a proper forum to litigate this lawsuit. Sanofi's contention that this lawsuit was only filed as a protective measure because it feared the Delaware action would be dismissed for lack of personal jurisdiction does not change this. Far from being a persuasive reason to transfer the litigation to Delaware, Sanofi's professed reason for suing in Florida is

indicative that Florida “is clearly the better forum, as all parties agree that both jurisdiction and venue lie here.” *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F.Supp.2d 484, 490 (E.D. Va. 2005); *see also Bristol-Myers Squibb Co. v. Andrx Pharms.*, No. 03 Civ. 2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (rejecting argument that second-filed lawsuit in the Southern District of Florida should not proceed because patentee only filed there out of fear that the situs of the first filed action would not have jurisdiction over one of the parties).

In *Bristol-Myers*, the court rejected the protective filing argument, placing particular reliance on the fact that the defendant company was located in Florida and that the “locus of operative facts” was centered there. Here, regardless of whether Sanofi’s lawsuit in Florida was protective, Florida is the more logical and convenient forum, where the situs of many of the alleged acts of infringement took place and where the Apotex Corp. documents and witnesses are located, and where a trial date has already been set for October of this year. Accordingly, Florida is where this case should be litigated.

Sanofi’s attempt to rely on the Delaware lawsuit’s filing date being a few days before this case as a basis for transferring this litigation is misplaced. The first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues. *Aventis*, 403 F. Supp.2d at 489 (E.D. Va. 2005) (explaining that the first-filed rule does not apply where the “Plaintiffs filed the same case against the same Defendants in two different courts.”); *Employers Reins. Corp. v. MSK Ins., Ltd.*, No. Civ. 01-2608-CM, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003) (declining to apply first-to-file rule, noting rule applies to “party who files first”); *see also (“Adams Resp. Therap. v. Mutual Pharm. Holdings*, No. 2:06-CV-04700-HAA-ES (D.N.J.) Dkt. No. 14, Nov. 16, 2006 Order at 2). (Exhibit C.) Rather, it most often applies to situations where two opposing parties race to different courthouses to file suits

against each other, a situation not present here. *See, e.g., Serco Serv. Co. v. Kelley Co.*, 51 F.3d 1037, 1039 (Fed. Cir. 1995); *Aventis*, 403 F. Supp. 2d at 489-90 (E.D. Va. 2005).

The cases Sanofi cites are factually opposite to the instant situation, and therefore offer no support for their assertion. For instance, *Philibert v. Ethicon, Inc.*, 2005 WL 525330 (S.D. Fla. Jan. 14, 2005), was cited by Sanofi for the proposition that a transfer to the first-filed forum where identical claims were pending would serve the interests of justice. Sanofi, however, fails to mention that the court only found the first-filed rule applied after determining that the Defendant, the moving party, did not show that the balance of convenience tipped in favor of transfer. *Philibert*, 2005 WL 525330 at *2. Additionally, Sanofi cites *Cordis Corp. v. Siemens-Pacesetter, Inc.*, 682 F.Supp. 1200 (S.D. Fla. 1987) to emphasize that a Plaintiff need not show a change of circumstances when moving to transfer. Sanofi omits the following facts. There were not two identical lawsuits pending. Plaintiff had originally filed suit naming an additional Defendant which destroyed jurisdiction in the transferee state. Only after dropping the additional defendant and gaining appropriate jurisdiction in the transferee state did the Plaintiffs request transfer. Most importantly, the Defendants admitted that all Defendant witnesses would be in the transferee state and the situs of the events leading to the lawsuit occurred in the transferee state.

None of these cases are factually applicable to the instant situation where Plaintiff filed two identical lawsuits, the convenience of the parties and witnesses and the situs of material events clearly weighs in favor of retaining the case in Florida and the expedited docket in Florida serve the interest of justice. The first filed rule is not absolute, and is subsidiary to the balancing of convenience and other interests. *Serco*, 51 F.3d at 1039. Thus, “the trial court’s discretion tempers the preference for the first-filed suit, when such preference should yield to the forum in which all interests are best served.” (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931,

938 (Fed. Cir. 1993)). For example, in *Aventis*, in rejecting the plaintiffs' first filed argument, the court explained that "its primary concern is to 'expedite the action' as directed by 21 U.S.C. § 355(c)(3)(C)." *Aventis*, 403 F. Supp.2d. at 490. There, the appropriate venue was determined to be the location (Virginia) of the second filed action where the person who was designated to accept service of process in the Paragraph IV certification letter was located. *Id.* at 488. Similarly here, Apotex, Inc.'s paragraph IV letter designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Suite 400, **Weston, Florida** 33326 as the person who would accept service on its behalf.

Adams similarly holds that the first-filed rule does not apply in a situation such as this, where the ANDA filer was sued in two different jurisdictions by the same patentee. There, the patentee (like Sanofi here), filed identical patent infringement actions against the ANDA-filer in both New Jersey and Pennsylvania. The ANDA-filer immediately answered and counterclaimed in Pennsylvania and consented to proceed there. The patentee objected. Invoking the first-filed rule, the patentee moved to stay the Pennsylvania action that it voluntarily filed, and asked the New Jersey Court to enjoin the Pennsylvania court from proceeding. The patentee's arguments were rejected and the second-filed Pennsylvania action was permitted to continue.

The "first-filed rule" is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient

Id.

The court in the second filed Pennsylvania action similarly rejected the patentee's arguments seeking to stay or transfer the action, explaining:

. . . I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which the Plaintiff almost exclusively relies – applies in the unique circumstances presented here . . . I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and

then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial.

Adams Resp. Therap. v. Mutual Pharm. Holdings, No. 2:06-cv-04418-PD (E.D. Pa.) Dkt. No. 31, Nov. 2, 2006 Order at 2) (Exhibit D).

Even if the first-filed rule had some application here, the fact remains that the Delaware and Florida litigations were filed within a few days of each other, so there is no prejudice to Sanofi with proceeding in Florida, which already is underway, as opposed to Delaware, which has yet to begin in earnest. By filing the second lawsuit in Southern District of Florida, and availing themselves of that forum, Plaintiffs accepted the possibility of having to litigate this case in Florida. No claimed hardship as a result of proceeding in Florida should be recognized by this Court.

IV. The Court Should Deny A Stay Of Litigation And Proceed With The Scheduling Order

Sanofi's alternative request that the Court stay this litigation and allow the Delaware action to move forward likewise should be denied. For all the reasons stated above this is will not serve the interests of justice. There is no rational reason to stay this litigation, which already is proceeding toward trial later this year, and allow the Delaware action to proceed. After receiving the Court's revised scheduling order of January 22, 2008 (Dkt. 23), Apotex moved the Delaware Court to transfer that case down to Florida or stay it pending resolution of this proceeding. With briefing on the transfer issue nearly complete and a trial date and discovery schedule already in place here, Apotex respectfully requests that this Court take the lead on deciding the transfer issue and deny Sanofi's motion so that the Delaware Court will have the benefit of this Court's ruling and accord it comity.

CONCLUSION

For the foregoing reasons, Sanofi's motion to transfer or stay its own Florida action should be denied together with such other relief as is appropriate under the circumstances.

Dated: January 28, 2008

Respectfully submitted,

s/. Jennifer Coberly

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Attorneys for Apotex Corp and Apotex Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by mail on January 28, 2008 on all counsel of record on the attached service list.

s/ Jennifer Coberly
Jennifer Coberly

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOPI-AVENTIS and
SANOPI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.

)
)
) Case No. 07 C 792
) Judge Sleet
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DECLARATION OF TAMMY McINTIRE

I, Tammy McIntire declare as follows:

1. I am President of Apotex Corp.
2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.
3. Apotex Corp. is a Delaware corporation whose headquarters and principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.
4. Apotex Corp. does not have any employees located in Delaware.
5. To the extent any Apotex Corp. employees are knowledgeable about ANDA No. 79-013 they are employed at the Florida location.
6. To the extent Apotex Corp. has any documents relevant to ANDA No. 79-013 they are located at Apotex Corp.'s Florida location.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 23, 2008



Tammy McIntire

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

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EXHIBIT B

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and)	
SANOFI-AVENTIS U.S. LLC,)	
)	Case No. 07 C 792
Plaintiffs,)	Judge Sleet
)	
)	
vs.)	
)	
APOTEX INC. and)	
APOTEX CORP.,)	
)	
Defendants.)	

DECLARATION OF BERNICE TAO

I, Bernice Tao declare as follows:

1. I am the Director, Regulatory Affairs U.S. for Apotex Inc. In that role, I am familiar with the various pending ANDA's that Apotex Inc has pending in the United States including ANDA 79-013.
2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry and information I have received in the course of my duties, and am competent to testify to the same.
3. Apotex Inc. is a Canadian corporation whose headquarters and principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.
4. Apotex Inc. is in the business of developing and manufacturing quality generic pharmaceuticals.
5. Apotex Inc. prepared and filed ANDA 79-013 from its offices in Canada.
6. Apotex Inc. does not have any employees located in Delaware.


7. To the extent any Apotex Inc. employees are knowledgeable about ANDA No. 79-013 they are employed at the Canadian location.

8. To the extent Apotex Inc. has any documents relevant to ANDA No. 79-013 they are located at Apotex Inc.'s Canadian location.

9. Apotex, Inc.'s paragraph IV letters designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Suite 400, **Weston, Florida** 33326 as the person who would accept service on its behalf.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: January 23, 2008



Bernice Tao

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

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EXHIBIT C

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EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ADAMS RESPIRATORY	:	CIVIL ACTION
THERAPEUTICS, INC.	:	
Plaintiff,	:	
	:	
v.	:	NO. 06-4418
	:	
PHARMACEUTICAL HOLDINGS	:	
CORP., et al.	:	
Defendants	:	
	:	

ORDER

AND NOW, this 2nd day of November, 2006, it is **ORDERED** as follows:

1. Plaintiff's Motion to Stay (Doc. No. 18), filed on October 24, 2006, is **DENIED**.

Plaintiff brings this action under the Hatch-Waxman Act, asking me to conclude that Defendants' intended manufacture and sale of a generic drug would violate Plaintiff's patent for the drug "Mucinex." See 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiff filed the instant Complaint only two days after filing a nearly-identical Complaint in the District of New Jersey. Adams Respiratory Therapeutics, Inc. v. Pharmaceutical Holdings Corp., Civ. Action No. 2:06-cv-04700-HAA-MF (D. N.J., filed October 2, 2006). Defendants have disputed jurisdiction in New Jersey, but concede that jurisdiction exists here. Plaintiff has explained that it filed in this Court so that it will have a "back-up" forum in the unlikely event that the New Jersey Court determines after Plaintiff's statutory forty-five day window has elapsed that the District of New Jersey is without jurisdiction to hear Plaintiff's first-filed action. See 21 U.S.C. § 355(j)(5)(B)(iii) (to stay FDA final approval of generic drug application, patent owner must bring suit within forty-five days of receiving notice that generic drug applicant has filed a certification that the patent is invalid or

not infringed). Plaintiff now seeks a stay of the instant matter, pending the New Jersey Court's decision on jurisdiction. Should that Court determine it is without jurisdiction, Plaintiff would then seek to proceed against Defendants in this Court.

Defendants vigorously contend that Plaintiff seeks a stay solely for delay, so that Plaintiff can take advantage of Hatch-Waxman's thirty month non-compete period. See id. (if patent owner files suit within forty-five day window, FDA will place a thirty-month automatic stay on approval of generic drug application, unless the Court issues a decision before expiration of thirty-month period). Plaintiff responds with equal vigor that Defendants have filed an Answer, Counterclaim, and Summary Judgment Motion (before Plaintiff even served the instant Complaint) to create the false impression that the action before me is well on its way to conclusion.

Without impugning the motives of Plaintiff or Defendants, I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which Plaintiff almost exclusively relies – applies in the unique circumstances presented here. The decisions Plaintiff has cited – in which the "first-filed" rule is applied – are inapposite. See Semmes Motors, Inc. v. Ford Motor Co., 429 F.2d 1197 (2d Cir. 1970) (plaintiff filed two cases in different districts, and defendant moved to stay); Old Charter Distillery Co. v. Continental Distilling Corp., 59 F. Supp. 528 (D. Del. 1945) (plaintiff filed two cases in different districts, and second court granted plaintiff's motion to stay after first court ruled that it had jurisdiction). I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial. Accordingly, I will deny the Motion to Stay.

2. Defendants' Motion for Summary Judgment (Doc. No. 10), filed on October 17, 2006, is **DENIED WITHOUT PREJUDICE** because it is premature. Defendants are free to renew their Motion at the close of discovery or at another appropriate time.

3. Defendants' Motion for Leave to File Trade Secrets and Confidential Business Information Under Seal (Doc. No. 11), filed on October 17, 2006, is **GRANTED**.

4. The Declarations of Harry G. Brittain and Robert Dettery, along with the attached exhibits, shall be maintained under seal and shall not be made available to the public, except as provided by subsequent Order of this Court.

5. Defendants shall file, as soon as practicable, a public record version of the Declarations of Harry G. Brittain and Robert Dettery with redactions of the portions of the declarations that contain the trade secret and confidential business information.

6. Defendants' Counterclaim (Doc. No. 4), filed on October 10, 2006, appears to turn entirely on the viability of Plaintiff's patent. Accordingly, resolution of the merits of Plaintiff's Complaint should precede resolution of the Counterclaim. Thus, Defendants' Counterclaim is **STAYED** pending resolution of the Plaintiff's claims.

IT IS SO ORDERED.

/s Paul S. Diamond, J.

Paul S. Diamond, J.

EXHIBIT DD

**BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

**IN RE ALFUZOSIN HYDROCHLORIDE
PATENT LITIGATION**

MDL Docket No. 1941

**DEFENDANTS ACTAVIS SOUTH ATLANTIC LLC'S
AND PAR PHARMACEUTICAL, INC.'S RESPONSE IN
SUPPORT OF MOTION TO TRANSFER AND CONSOLIDATE**

Defendants Actavis South Atlantic LLC ("Actavis") and Par Pharmaceutical, Inc. ("Par") respectfully submit this response in support of Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC's (collectively, "sanofi") February 1, 2008 Motion to Transfer and Consolidate for Pretrial Proceedings ("sanofi's Motion"). Transfer and consolidation of the related actions for pretrial proceedings would promote the just and efficient conduct of the actions, conserve judicial resources and satisfy the purpose of the Hatch-Waxman Act by treating all first filers the same.

The four cases sanofi seeks to consolidate include three actions pending in the District of Delaware, Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al., No. 07-572 (GMS) (MPT), Sanofi-Aventis et al. v. Barr Laboratories, Inc., No. 07-754 (GMS) (MPT), and Sanofi-Aventis et al. v. Apotex Inc. et al., No. 07-792 (GMS) (MPT) (collectively, the “Delaware Actions”), as well as an action pending in the Southern District of Florida, Sanofi-Aventis et al. v. Apotex Inc. et al., No. 07-61800-CIV (S.D. Fla.) (the “Florida Action”) (collectively, the “Related Actions”).

All four cases involve the alleged infringement, validity and enforceability of two sanofi patents, U.S. Patent No. 4,661,491 (“the ‘491 patent”) and U.S. Patent No. 6,149,940 (“the ‘940 patent”). The Related Actions are all at the early stages of pretrial discovery, and no undue prejudice will be imposed upon Apotex or any of the other defendants by consolidation. Given the overlapping issues, consolidation is appropriate. Moreover, if these actions are not consolidated, Actavis, Par and other first filers may be unfairly prejudiced.

RESPONSES TO SANOFI’S AVERMENTS

In response to the averments in sanofi’s Motion, Actavis and Par, pursuant to Rule 7.1(b), respond as follows:

1. Admit.
2. Admit except that Actavis and Par do not have sufficient information to either admit or deny whether the ‘491 and ‘940 patents “cover” Uroxatral®.
3. Actavis and Par admit that Actavis filed an ANDA for a generic version of in the Summer of 2007 seeking to market its ANDA product before the expiration of the

'491 and '940 patents. Actavis and Par do not have sufficient information to either admit or deny the truth of the remaining allegations in this averment.

4. Actavis and Par admit that Actavis filed an ANDA with a Paragraph IV certification, asserting that the claims of the '491 and '940 patents are invalid and/or not infringed by the manufacture, use or sale of the proposed ANDA product. Actavis and Par do not have sufficient information to either admit or deny the truth of the remaining allegations in this averment.

5. Actavis and Par do not have sufficient information to either admit or deny the truth of this averment because it involves communications between Apotex and sanofi.

6. Deny as to Actavis and Par. Actavis and Par do not have sufficient information to admit or deny the truth of this averment with respect to the filing of ANDAs by other defendants.

7. Admit that sanofi commenced the named actions. Actavis and Par do not have sufficient information to admit or deny sanofi's motivation for commencing these actions.

8. Admit.

9. Admit only that sanofi commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex, Inc, and Apotex Corp. (collectively, "Apotex") in Delaware on December 6, 2007 for infringement of the '491 patent, and that this action was designated as related to the earlier-filed Delaware complaints and assigned to the same Judge and Magistrate Judge. Actavis and Par do not have sufficient information to either admit or deny that Apotex's second paragraph IV certification was dated October 25, 2007, or that

Apotex alleged therein that its proposed generic product did not infringe any valid claim of the '491 patent.

10. Admit.

11. Actavis and Par do not have sufficient information to admit or deny whether sanofi met its asserted deadline with respect to 13 defendants. The remaining content of Paragraph 11 of the sanofi motion reflects sanofi's view of the law rather than an averment, and thus no further response need be given.

12. Actavis and Par do not have sufficient information to admit or deny this averment because it is based on sanofi's beliefs or concerns regarding personal jurisdiction.

13. Admit that the District of Delaware can properly exercise personal jurisdiction over Actavis and Par. Actavis and Par do not have sufficient information to admit or deny that the District of Delaware can properly exercise jurisdiction over the remaining defendants. Actavis and Par admit that sanofi brought second-filed actions against Aurobindo, Mylan, Sun, and Torrent shortly after the first two Delaware actions were filed in September 2007 and against Apotex on December 10, 2007. Actavis and Par do not have sufficient information to admit or deny the remaining allegations in this averment because they are based on sanofi's beliefs or concerns regarding personal jurisdiction.

14. Actavis and Par do not have sufficient information to admit or deny this averment, because it is based on communications between Apotex and sanofi.

15. Admit.

16. Admit.

17. Admit.

18. Admit.

19. Admit.

20. Admit.

21. Agree with the relief requested by sanofi that the Panel transfer the Florida action to the District of Delaware and consolidate it for coordinated pretrial proceedings with the three Delaware actions.

ARGUMENT

I. The Related Actions Should Be Consolidated Pursuant to Section 1407

A. The Related Actions Involve Common Questions of Fact and Law

The Related Actions should be consolidated because they involve many common issues, including claim construction, validity and enforceability issues relating to the '491 and '940 patents. Cases involving common questions of fact should be consolidated for pretrial proceedings when the transfer would "be for the convenience of parties and witnesses and [would] promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a) (2008); In re Desloratadine Patent Litig., 502 F. Supp. 2d 1354, 1355 (J.P.M.L. 2007). Transfer and consolidation do not require "complete identity or even a majority of common factual or legal issues." In re Kugel Mesh Hernia Patch Prods. Liab. Litig., 493 F. Supp. 2d 1371, 1374 (J.P.M.L. 2008). To the extent that non-common issues are involved, the transferee court can address those through pretrial procedures such as separate but concurrent discovery tracks. Id.

The Panel has repeatedly transferred and consolidated actions involving the alleged infringement of a patent by defendants seeking to make a generic version of a

pharmaceutical product. See, e.g., In re Desloratadine Patent Litig., 502 F. Supp. 2d 1354 (J.P.M.L. 2007); In re Rivastigmine Patent Litig., 360 F. Supp. 2d 1361 (J.P.M.L. 2005); In re Omeprazole Patent Litig., MDL No. 1291, 1999 U.S. Dist. LEXIS 12589 (J.P.M.L. 1999).

Here, the Related Actions involve many common issues, including claim construction, validity and enforceability of the '491 and '940 patents. Both the Delaware and Florida courts will have to engage in a claim construction analysis of both patents, which involves analyzing the language of the relevant claims of each patent, the patents' specifications and the file histories of each patent. Claim construction could potentially include the consideration of extrinsic evidence as well, including scientific treatises and dictionaries and expert and inventor testimony. Common resolution of these issues would prevent inconsistent rulings that could prejudice Actavis, Par and the other defendants.

B. Consolidation Would Promote the Just and Efficient Resolution of the Related Actions

Consolidation of the Related Actions would promote the just and efficient resolution of the actions because it would "eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to time-consuming and complex matters of claims construction; and conserve the resources of the parties, their counsel and the judiciary." In re Desloratadine Patent Litig., 502 F. Supp. 2d at 1355.

Consolidation of the Related Actions would conserve judicial resources, as it would require only one court to engage in the time- and labor-intensive tasks of analyzing the patents at issue, construing their claims and resolving the parties' disputes. Consolidation would also obviate the possibility of inconsistent pretrial rulings, which would not only

be fundamentally unfair to the parties, but which could also engender further appellate practice, thus consuming further judicial resources.

Transfer and consolidation are especially desirable here, where all four Related Actions are at a similar stage, and where no significant discovery has taken place. According to sanofi's Motion, Apotex has served one set of document requests, but no other discovery has been exchanged between any of the parties. Given that many common issues of fact exist in all four Related Actions, discovery will substantially overlap. If the cases are consolidated, the transferee court can order common discovery on the overlapping issues, avoid the need for multiple and duplicative discovery and limit the number of discovery motions that would need to be filed.

C. Consolidation Would Best Serve
the Convenience of the Parties and Witnesses

Finally, transfer and consolidation is warranted under Section 1407 because it would be more convenient for the parties and witnesses, and would likely produce substantial cost savings for each party. Specifically, because the testimony of many witnesses is likely to be needed in more than one of the Related Actions, consolidation would prevent the need for multiple depositions of each witness. See In re Inter-Op Hip Prosthesis Prods. Liab. Litig., 149 F.Supp.2d 931, 933 (J.P.M.L. 2001) (stating that consolidation would result in "an overall savings of cost and a minimum of inconvenience to all concerned").

II. Consolidation Would Satisfy the Purposes of the Hatch-Waxman Act

Consolidation of the Related Actions would also be consistent with the incentive structure established by the Hatch-Waxman Act by treating all first generic filers the same. Through the Hatch-Waxman Act, Congress established an incentive structure to

encourage generic applicants to challenge brand patents with the express purpose of enhancing generic market competition. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2008); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1071 n. 11 (D.C. Cir. 1998) (exclusivity grant an important incentive); see also Understahl, B., Authorized Generics: Careful Balance Undone, 16 Fordham Intell. Prop. Media & Ent. L.J. 355, 365 (2005). The 180-day exclusivity period was the cornerstone of this incentive structure. Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 44 (D.D.C. 2000) (“The 180-day exclusivity provision was specifically adopted to reward generic drug makers who . . . undertake the potentially time-consuming and costly efforts to establish that a pioneer drug maker’s patent is wrongfully keeping generic drugs off the market.”); see also Understahl, B., 16 Fordham Intell. Prop. Media & Ent. L.J. at 365.

According to sanofi’s Motion, “each of the nine separate ANDAs seeking approval to market a copy of sanofi-aventis’s Uroxatral[®] brand drug product was filed on the same day, and thus each of the ANDA filers is a ‘first-filer’ eligible for the 180 day exclusivity.”¹ (Sanofi Motion at 19.) Assuming this is true, each first-filer defendant should be treated the same.

If the Apotex Florida Action is not consolidated with the other Related Actions, Apotex could obtain an unfair advantage, to the detriment of the other first filers. For example, FDA approval of all of the ANDAs was automatically stayed by 30 months when sanofi filed suit within 45 days of receiving notice from the first filers that the ANDAs had been filed. 21 U.S.C. §355(j)(5)(B)(iii). This 30-month stay will be terminated, however, upon a district court decision finding the relevant patent invalid or

¹ Actavis and Par do not have any information to corroborate whether each ANDA was, in fact, filed on the same day and whether each ANDA filer is entitled to the 180-day exclusivity period.

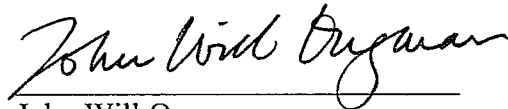
not infringed. 21 U.S.C. §355(j)(5)(B)(iii)(I). Under this structure, if Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.

CONCLUSION

For the foregoing reasons, Actavis and Par respectfully request that this Panel transfer the Florida action Sanofi-Aventis et al. v. Apotex Inc. et al. to the District of Delaware and consolidate that action with the three Delaware actions, Sanofi-Aventis et al. v. Actavis South Atlantic LLC et al., Sanofi-Aventis et al. v. Barr Laboratories, Inc., and Sanofi-Aventis et al. v. Apotex Inc. et al., for coordinated pretrial proceedings.

Dated: February 25, 2008

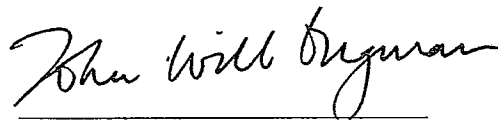
Respectfully submitted,

A handwritten signature in black ink, reading "John Will Ongman". The signature is fluid and cursive, with a horizontal line drawn underneath it.

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CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Response in Support of the Motion to Transfer and Consolidate were mailed via first-class mail on February 25, 2008 to the counsel of record in the associated cases listed in the attached Panel Attorney Service List.

A handwritten signature in cursive script, reading "John Will Ongman", written in black ink. The signature is positioned above a horizontal line.

John Will Ongman

Judicial Panel on Multidistrict Litigation - Panel Attorney Service List

Page 1

Docket: 1941 - IN RE: Alfuzosin Hydrochloride Patent Litigation

Status: Pending on / /

Transferee District: Judge:

Printed on 02/15/2008

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(Panel Attorney Service List for MDL 1,941 Continued)

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